FRED HUTCH
Institutional Review Board

Policy/Procedure

Title:	Approval Date Guidelines and Turnaround Times
Policy:	1.8
Version:	9.00
Effective Date:	January 21, 2019
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director Karen Hansen 12/21/18 *Signature/date*

Version History	Effective Date
8.01	07-03-2017
8.00	11-26-2014
7.00	09-01-2012
6.02	01-31-2012
6.01	05-17-2010
6.00	03-29-2010
5.00	01-14-2008
4.00	08-01-2007
3.00	05-17-2007
2.00	01-19-2007
1.01	01-19-2007
1.00	11-30-2006

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research Center (Fred Hutch) Institutional Review Office (IRO) that Institutional Review Board (IRB) approved activities are given approval dates per the *Approval Date Guidelines* (083). *IRB Turnaround Times* (0411) provides the turnaround time for IRO staff to process and to provide the approval documents to principal investigators (PI) in a timely manner.

DEFINITIONS

None

PRINCIPLES/OVERVIEW

The *Approval Date Guidelines* (083) are used by the IRO staff to determine the approval dates for all activities related to IRB review (e.g., new applications, continuing review reports, modifications, etc.). 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.

Fred Hutch intends to maintain a fixed anniversary date for conducting continuing review of research after the initial review.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch, investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval, study monitors, and auditors or sponsors.

PROCEDURES

1. Approval Date Guidelines

a. The *Approval Date Guidelines* (083) document outlines the approval dates given for different outcomes resulting from the IRB review and approval process.

b. IRB documents receiving "approved from date" and "approved to date" are:
   i. *Application for Review Interventional Research* (0324)
   ii. *Application for Review Observational Research* (0325)
   iii. *Application for Review Human Specimens or Data Research* (0326)
   iv. *Continuing Review Report* (045)

   Note: For research studies subject to only the 2018 Requirements of the Common Rule, and for which Continuing Review is not required (as outlined in *IRB Policy 2.28 Status Reports for IRB Files* [0403]), the *"approved to date"* will be noted as "N/A".

c. IRB documents receiving "IRB Chair signature date" are:
   i. *Allegation of Human Subjects Research Noncompliance Reporting Form* (0297)
   ii. *Expedited Reporting Form for Unanticipated Problems or Noncompliance* (0203)
   iii. Miscellaneous memos
   iv. *Emergency Treatment Acknowledgement Report* (047)
   v. *HIPAA Supplement and Waiver of Authorization* (0208)
   vi. *Waiver of Consent Supplement* (0202)
   vii. *Research Modification Form* (062)
   viii. Closure reports

2. Determining Approval Dates at Initial Review

Note: The below "approved to date" information for either Full or Expedited Review will not apply to studies determined to not require Continuing Review according to the 2018 Requirements of the Common Rule. (Please see *IRB Policy 2.28 Status Reports for IRB Files* [0403] for further details.)

a. Full review: The "approved from date" is the IRB Committee meeting "agenda date," and the "approved to date" is one full year from the "agenda date." The "approved to date" indicates the day when study activities must stop. For example, if a study is approved from 10/2/2016 to 10/2/2017, the study may use its approved documents, such as an approach letter or consent document, until midnight on 10/1/2017. No research activity may be conducted on the "approved to date."

The “signature date” for full review activities is the date the IRB Chair or designee signed the final approved documents.

i. Full review items approved at a convened meeting “as submitted”: When the full IRB approves an item “as submitted” with no modifications required, the “signature date” is the same as the IRB Committee meeting “agenda date”. For example, if the IRB Committee meeting was 1/10/2016 and the new application was approved as submitted, the approval period for the new application is 1/10/2016 to 1/10/2017.

ii. Full review items originally approved at a convened meeting with minor modifications required: When the IRB Chair or designee reviews and approves the PI’s response to minor modifications required by the IRB Committee, the "signature date" represents when the IRB Chair or designee reviews and confirms the PI responses and revisions satisfy the minor modifications required by the IRB Committee.

The “approved from date” in this scenario is the IRB Committee meeting “agenda date.” For example, if the IRB approved the study with minor modifications required at a meeting on 1/20/2016, and the IRB Chair reviewed and approved the PIs response on 1/29/2016, the initial approval period for this study is 1/20/2016 to 1/20/2017. The “signature” date is 1/29/2016, which is the date the IRB Chair or designee confirmed the minor modifications were satisfied and signed the approved documents.

b. Expedited review: The “approved from date” is the same date as the “signature date” when the expedited reviewer approved the study. The “approved to date” is one full year from the “signature date.” For example, if the IRB expedited reviewer approved the study on 1/10/2016, the approval period is 1/10/2016 to 1/10/2017.

3. Determining Approval Dates at Continuing Review

The IRB intends to retain a set anniversary date for continuing review throughout the life of the study. At the time of continuing review, IRB staff follow the *Approval Date Guidelines* (083) document to determine the new “approved from” and “approved to” dates as well as the “signature date.”

a. If the continuing review report is approved with or without modifications required <u>within 30 days</u> of the current “approval to date,” the anniversary date stays fixed and the new “approval to date” is one full year from the prior year’s “approval to date”. For instance, if a study is currently approved from 10/20/2016 to 10/20/2017 and the IRB conducts continuing review and approves the study for another year on 10/5/2017, the new approval period is 10/20/2017 to 10/20/2018. The “document release date” is either the IRB meeting “agenda date” if the continuing review was approved as submitted; or the “signature date” if the continuing review was approved with minor modifications which needed subsequent confirmation of completion by the IRB Chair or designee.

b. If the continuing review report is approved with or without modifications required <u>outside of 30 days</u> prior of the current “approval to date,” the anniversary date is reset and the new “approval to date” is one full year from the “agenda date.” For example, if a study is currently approved from 10/20/2016 to 10/20/2017 and the IRB conducts continuing review and approves the study for another year on 9/5/2017, the anniversary date is reset and the new approval period is 9/5/2017 to 9/5/2018. The “document release date” is the either the IRB meeting “agenda date” if the continuing review was approved as submitted; or the “signature date” if the continuing review was approved with minor modifications which needed subsequent confirmation of completion by the IRB Chair or designee.

4. Stamping IRB Approved Documents

a. The "document release" stamp is applied to the protocol, Investigator Brochure, and all subject materials. The "document release" date is the same as the "signature date."

b. Consent Documents: The "document release" stamp is also applied to all consent forms when accrual is continuing in the study. The "document release" date is the same as the "signature date" in all scenarios where accrual is continuing.

5. Correcting Wrong Approval Dates

a. When an activity (e.g., continuing review report) is given incorrect approval dates, the *Correction Memo* (089) is forwarded to the PI/contact person notifying them of the corrective actions taken, along with the corrected documents. The IRO staff uses a blue or black ink pen, draws a single line through the incorrect date(s), and adds the correct dates, their initials, and the date of correction.

b. The database is updated with the correct dates in the appropriate tab. In addition, a 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 = IRO Staff
   - Comment field = Corrected approval dates on <insert type of activity>
   - Agenda date = next agenda date

c. 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.

6. IRB Turnaround Times

IRB Turnaround Times (0411) indicates 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.

SUPPORTING DOCUMENTS

IRB Policy 2.28 Status Reports for IRB Files (0403)
Allegation of Human Subjects Research Noncompliance Reporting Form (0297)
Application for Review Human Specimen or Date Research (0326)
Application for Review Interventional Research (0324)
Application for Review Observational Research (0325)
Approval Dates Guidelines (083)
Continuing Review Report (045)
Correction Memo (089)
Emergency Treatment Acknowledgement Report (047)
Expedited Reporting Form for Unanticipated Problems or Noncompliance (0203)
HIPAA Supplement and Waiver of Authorization (0208)
IRB Turnaround Times (0411)
Research Modification Form (062)
Waiver of Consent Supplement (0202)

REFERENCES

FDA Guidance: IRB Continuing Review after Clinical Investigation Approval
OHRP Compliance Activities: Common Findings and Guidance (July 10, 2002) - #42
OHRP Guidance on IRB Continuing Review of Research
OHRP Guidance on Written IRB Procedures