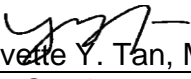





SOP 5 MANAGEMENT OF APPEAL OF CRERC DECISION

Supersedes:	Version 04.1 (17 May 2019)	
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5. Management of Appeal of CRERC Decision

5.1 Management of Appeal of CRERC Decision



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1. Objective of the Activity

To describe the procedures for the review of appeal of CRERC decision on its review of a study protocol *to ensure fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the Researcher/Principal Investigator (PI).*

2. Scope

This SOP applies to the management of appeal of CREC decision on its review of a study protocol in compliance with ICH-GCP 2018 3.3.9(c) and CIOMS 2016 - Guideline 23. *The SOP starts with the receipt of the letter of appeal and ends with the filing of the letter of appeal and related documents and the updating of the protocol file index.*

3. Responsibilities

The Administrative Secretary is responsible for a) receiving and recording the letter of appeal of CRERC decision from the Researcher/PI; b) informing the CRERC Chair and Member-Secretary of the letter; c) forwarding the letter of appeal and other relevant documents to the Primary Reviewers; d) following up the results of the review from the Primary Reviewers, e) Including the appeal in the agenda of the forthcoming meeting; f) distributing a copy of the letter of appeal to the CRERC Members with the Notice of Meeting, g) preparing the Notification of CRERC decision using the appropriate form of the protocol submission for which the appeal is raised; h) filing the documents in the protocol file folder and updating the protocol file index.

The CRERC Chair is responsible for a) designating Primary Reviewers if those who did the initial review are not available, and b) reviewing, signing and dating the communication to the Researcher/PI.

The Primary Reviewers are responsible for a) assessing the merit of the appeal b) returning the accomplished assessment checklist or results of the review with the other documents in the package to the CRERC Administrative Secretary within the specified timeline.

4. Workflow

No.	Activities	Person/s Responsible
1	Receive the letter of appeal	Admin-Secretary
2	Identify the Primary Reviewers and forward the letter of appeal and other relevant documents to the Primary Reviewers	Administrative Secretary
3	Review the appeal	Primary Reviewers
4	Include the appeal in the agenda of the forthcoming meeting	Administrative Secretary



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5	Communicate CRERC decision to Researcher/PI	Admin-Secretary, CRERC Chair
6	File the letter of appeal and related document in the protocol file folder, and update the protocol file index	Administrative Secretary

5. Detailed Instructions

5.1 *Receive the letter of appeal*

5.1.1 If the Researcher/Principal Investigator (PI) disagrees with the recommended revisions or the review decision made by the CRERC s/he may submit a written appeal for reconsideration of the decision addressed to the CRERC Chair. The appeal should include the reason for requesting reconsideration and should contain supplemental documentation in support of the arguments made in the appeal.

5.1.2 *The Administrative Secretary verifies if the letter of appeal is still within 30 calendar days from the date of the Notification of CRERC decision on the last review of the protocol concerned.*

5.1.3 *If the submission of the appeal is still valid, the Administrative Secretary stamps "Received" and the date of receipt on the letter of appeal and gives the duplicate copy to the Researcher/PI or its representative.*

5.1.4 *The Administrative Secretary records the submission in Form 9.1 Log of Protocol Related Submissions and e-mails the letter of appeal to both the Chair and the Member Secretary.*

5.2 *Identify the Primary Reviewers and forward the letter of appeal and other relevant documents to the Primary Reviewers*

5.2.1 *The Administrative Secretary identifies the Primary Reviewers who did the initial review of the study protocol.*

5.2.2 *The CRERC Chair designates Primary Reviewers if those who did the initial review are not available.*

5.2.3 *The Administrative Secretary forwards by e-mail to the Primary Reviewers within seven (7) days from the receipt of the letter of appeal together with the scanned copy of the protocol and documents related to the last review, and blank copy of appropriate assessment checklist after the document package is logged in CRERC Form 9.2 Log of Outgoing Protocol Related Communications.*

5.3 Review the appeal

5.3.1 The Primary Reviewers assess the document package whether there is sufficient basis to consider the appeal.

5.3.2 *The Primary Reviewers return the accomplished assessment checklist/result of the assessment and the rest of the documents in the package within seven (7) calendar days of their receipt of the document package.*



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- 5.4 Include the appeal in the agenda of the forthcoming meeting
 - 5.4.1 The deliberation on whether to consider the appeal will be reviewed and voted upon during a Full Committee meeting (Refer to SOP 4.2 Full Committee Meeting)
 - 5.4.2 The Administrative Secretary includes the appeal in the agenda of the forthcoming meeting and distributes the letter of appeal together with the Notice of Meeting.
 - 5.4.3 The Researcher/PI may be requested to appear before the CRERC *en banc* to present his or her appeal and any supporting literature/information or newly obtained documentation. S/he cannot participate in the deliberation.
 - 5.4.4 During the deliberation of the appeal, the medical/scientific Primary Reviewer presents the results of the assessment during the Full Committee meeting.
 - 5.4.5 *Review decision depends on the type of protocol submission (e.g. appeal of CRERC decision after initial review, after review of resubmission, or after review of any of the post-approval submissions) for which the appeal is raised.* (Refer to section 5.3.1 of SOP 4.2 Full Committee Review for possible review decisions per type of submission)
- 5.5 Communicate CRERC decision to Researcher/PI
 - 5.5.1 The Administrative Secretary prepares the Notification of CRERC Decision based on the minutes of the meeting, for review and signature of CRERC Chair, and sends it to the Researcher/PI within 5 days from the date of the meeting after recording the document in the CRERC Form 9.2 Log of Outgoing Protocol Related Communications. (Refer to SOP 8.2 – Communicating CRERC Decision)
 - 5.5.2 The CRERC Form to use depends on the type of submission for which the appeal was made. (Refer to section 5.1.4 of SOP 8.2 Communicating CRERC Decision)
- 5.6 File the letter of appeal and related documents in the protocol file folder, and update the protocol file index and the protocol database
 - 5.6.1 The Administrative Secretary files the letter of appeal and its attachments (if any), completed assessment checklist, excerpt of the minutes of the meeting, and duplicate copy of the Notification of CRERC decision in the protocol file folder and updates the protocol file index and the protocol data base if the appeal is related to an initial review, review of resubmission, review of application for protocol amendment, continuing review, or review of final report.

6. Related Forms

- CRERC Form 9.1 *Log of Protocol Related Submissions*
CRERC Form 9.2 *Log of Outgoing Protocol Related Communications*



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7. SOP Document History

Version No.	Version Date	Description of Changes
01	23 Jan 2015	Refer to SOP v. 01
02	21 May 2015	Refer to SOP v. 02
03	05 Feb 2016	Refer to SOP v. 03
04.1	18 May 2018	Refer to SOP v. 04.1
05	31 Oct 2021	<ul style="list-style-type: none"> ▪ Changed Purpose to Objective, and Process Flow/Steps to Workflow to harmonize with PHREB's section titles. ▪ Added in the section on Scope, a description of the start and end tasks of the SOP ▪ Added the detailed responsibilities of the CRERC Chair, Primary Reviewers and those of the Administrative Secretary ▪ Added Task #1 – Receipt of the letter of appeal against CRERC decision of last review; 5.1.2 – checking whether the date of the letter of appeal is within the grace period of 30 calendar days; 5.1.3 – stamping “Receipt and date of receipt” on the duplicate copies of the letter; 5.1.4 – logging in the submission ▪ Added Task #2 – Identification of the Primary Reviewers and forwarding of document package for their review ▪ Added timelines: from date of receipt of submission to forwarding this to Primary Reviewers in 5.2.3; from receipt of document package for review by Primary Reviewers to return of results of assessment to CRERC in 5.3.2; from date of meeting to sending of communication to Researcher/PI ▪ New forms – Form 9.1 Log of Protocol Related Submissions, CRERC Form 9.2 Log of Outgoing Protocol Related Communications ▪ Used Administrative Secretary instead of CRERC Secretariat