

Title:	Review of case reports and case series		
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Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide criteria to determine if a study case or case series qualifies for review and provide instructions on management, review and approval of a case or case series through the expedited review process by ratification in full board.

2. Scope

This SOP applies to the review and approval of case or case series and documents, which qualify for expedited review by ratification in full board by the IEC.

3. Responsibility

It is the responsibility of the Member Secretary / Chairperson of the Institutional Ethics Committee (IEC) to determine if a case / case series qualifies for an expedited / full board review and if required designate one / two primary reviewers. Designated IEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the case / case series and related documents within the given time frames. The Member Secretary / Chairperson are responsible to take the decision.

3.1 Secretariat of the Institutional Ethics Committee

The secretariat will receive and verify the following documents and will forward these documents to the member secretary for further course of action.

- i. A request / cover letter signed by the faculty / investigator forwarded by Head of the Department to IEC for review.
- ii. The manuscript in its entirety.
- iii. Images accompanying case report/case series (e.g. clinical and imaging)
- iv. Xerox copy of written consent from the patient if prospective.

4. Activity Table

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine case / series for expedited / full board review	Member Secretary/Chairperson
3.	Review of case study/series	Designated IEC Member
4.	Decision of IEC	Secretary/Chairperson
5.	Communicate with the IEC and the Investigator	IEC Secretariat

5. Detailed instructions

5.1 Process of IEC review and requirements from investigator /faculty

1. The case report or case series should be submitted **BEFORE** submitting to a peer reviewed journal along with the processing fees.
2. The submission should include –
 - i. A request / cover letter to IEC for review forwarded by HOD
 - ii. The manuscript in its entirety
 - iii. Written consent from the patient in case of prospective case.
(In the event that the patient is deceased, consent from the next of kin must be included in the submission. In case the next of kin cannot be traced, the investigator must provide evidence that every effort was made to contact the relative/next of kin and that failed)
 - iv. IEC review charges: The review processing fees shall be collected as Rs 500/- for case series and Rs 250/- for case reports. The payment details will be given to the writer via email once the submission is complete.
3. The case report/case series should not have ANY personal identifiers.

4. If an identifier is required for the case report/case series for advancing medical knowledge [for example the face is not fully hidden], then the consent form must state that so that the patient/next of kin is aware of the same.
5. Images accompanying case report/case series (e.g. clinical and imaging)
6. The CARE guidelines for the manuscript must be followed.

5.2 Review protocol & give comments and recommendations.

Member Secretary in consultation with chairperson will send the case / case series for review to designated EC member to give their comments and recommendations to the secretariat within seven days from date of receipt of the proposal.

5.3 Decision of IEC

- Decision about approval will be taken by the member secretary in consultation with Chairperson.
- Decision will be communicated to investigator/ faculty within 14 working days of receipt of proposal.
- The decision will be informed to the IEC members at the next full board meeting.
- If deemed necessary by Primary reviewers, Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full board meeting.
- The review process should be completed and the reply should be given within 14 working days. If by any reason the case / series is taken for full board, then the decision will be communicated within 14 working days after full board meeting.

5.5 Communicate with the IEC and the investigator/faculty.

- The Secretariat will send the no objection letter via mail or Hard copy to the faculty /Investigator if the case / series has no objection.
- If case / series is disapproved or requires resubmission after certain modifications or clarification, this will be informed to the faculty / Investigator. The reasons for disapproval of a case / series will be specified in the letter sent to faculty / Investigator via email or hard copy.

6. Glossary

Case report	A report of 1-2 patients; usually 800-1500 words
Case series	A report of more than 2 patients. Word count will depend upon the journal