GUIDANCE FOR CASE REPORT SUBMISSION

Institutional Review Board / Research Ethics Committee

Version 1.0 | For Novice Researchers

1. What Is a Case Report?

A case report is a detailed account of the clinical presentation, diagnosis, treatment, and outcome of a single patient (or a small series of patients) that offers a unique or instructive learning point. Case reports are an established form of medical evidence — they can introduce new diseases, highlight rare presentations, document unexpected drug reactions, or share novel treatment strategies.

Because case reports involve identifiable patient information, they require formal review and approval by the Institutional Review Board (IRB) or Research Ethics Committee (REC) before any data is collected, written up, or submitted for publication.

2. Do I Need IRB / REC Approval?

The short answer is: yes, in almost all circumstances. Before you begin writing, answer these questions:

Single patient	IRB review required. Written informed consent from the patient is mandatory unless a waiver is granted.
2–10 patients	Formal IRB approval required. Each patient must consent individually.
>10 patients	This is likely a case series or retrospective study — full IRB review protocol required.
Deceased patient	IRB review still required. Next-of-kin consent or a waiver must be documented.

If you are unsure whether your case qualifies for an expedited or exempt review, contact the IRB/REC office before proceeding. Do not assume exemption.

3. What to Submit to the IRB / REC

Your submission package must include all of the following:

- Completed IRB application form (available from the office or institutional portal)
- De-identified case summary (no names, dates of birth, or identifiers in the draft)
- Signed patient informed consent form (or justification for waiver request)
- CARE checklist (see Section 4) — completed and signed by the submitting author
- Draft manuscript or structured case write-up
- Curriculum Vitae (CV) of the principal author/clinician
- Any supporting images, investigations, or pathology reports (de-identified)

4. The CARE Checklist — A Required Reporting Standard

The CARE Checklist (CAse REport guidelines) is an internationally recognised, peer-reviewed framework for writing complete and transparent case reports. Our IRB/REC requires that every case report submission include a completed CARE checklist.

The checklist ensures your report contains all the information reviewers and readers need to evaluate the case. It is not optional — incomplete submissions without the CARE checklist will be returned without review.

#	CARE Item	Requirement
1	**Title**	The words 'case report' should appear in the title
2	**Keywords**	2–5 keywords including 'case report'
3	**Abstract**	Introduction, case presentation, conclusion (~150 words)
4	**Introduction**	Medical background and rationale for this case report
5	**Patient Information**	De-identified demographics, chief complaint, medical history
6	**Clinical Findings**	Relevant physical examination and clinical findings
7	**Timeline**	Chronological summary of key events in a table or figure
8	**Diagnostic Assessment**	Diagnostic methods, differential diagnoses, final diagnosis
9	**Therapeutic Intervention**	Treatment types, dosages, duration
10	**Follow-up & Outcomes**	Patient outcomes, adverse events, patient-reported outcomes
11	**Discussion**	Strengths, limitations, relevant literature, conclusions
12	**Patient Perspective**	Patient's perspective on the experience (where applicable)
13	**Consent**	Confirmation that patient consent was obtained

The full CARE guidelines and downloadable checklist are available at: www.care-statement.org

5. Patient Consent — Key Requirements

Informed consent is a cornerstone of ethical case reporting. The following principles apply:

- Consent must be obtained before any identifiable data is recorded for publication purposes.
- The patient must be informed of: (a) what information will be shared, (b) where it will be published, and (c) that participation is voluntary.
- Use the institution's standard Case Report Consent Form — do not create your own.
- Consent from a minor requires parent/guardian signature plus, where appropriate, the child's assent.
- If the patient is deceased, contact the IRB/REC office for guidance on next-of-kin consent.
- Retain the signed consent form in the patient's file and submit a copy with your IRB application.

6. De-identification Standards

All drafts submitted to the IRB/REC must be fully de-identified. Remove or anonymise the following:

- Patient name, initials, date of birth, and age (use age range, e.g. '40s')
- Dates of clinical events (use relative timeframes: 'Day 1', 'Week 3', 'Month 6')
- Geographic identifiers (hospital name, city, country)
- Unique identifiers: hospital numbers, ID numbers, health record numbers
- Photographs: crop, blur, or apply eye-bars to facial images unless the patient explicitly consents to identification

Note: De-identification does not replace consent. Even anonymous reports require IRB review.

7. Timelines and Review Process

Step 1	Complete IRB application + assemble full submission package
Step 2	Submit via the institutional portal or by email to the IRB office
Step 3	Expedited review: approximately 10–15 working days (single case)
Step 4	Receive approval letter — do not begin writing the final manuscript before this step
Step 5	Submit manuscript for publication; include IRB approval number in the methods section

Approval letters are valid for 12 months. If the manuscript has not been submitted for publication within 12 months, contact the IRB/REC for renewal.

8. Common Reasons for Rejection or Delay

- Missing or incomplete CARE checklist
- Consent form not submitted or incorrectly signed

- Identifiable patient information present in the draft manuscript
- No clear statement of what makes this case unique or instructive
- Inadequate literature review or missing differential diagnoses
- Photographs not de-identified

9. Resources and Contacts

- CARE Guidelines: www.care-statement.org
- EQUATOR Network (all reporting guidelines): www.equator-network.org
- IRB/REC Application Portal: [insert institutional link]
- IRB/REC Office Email: [insert institutional email]
- Consent Form Template: Available from the IRB/REC office on request

If you are a novice researcher, we strongly encourage you to reach out to the IRB/REC office before starting your write-up. Early guidance prevents delays and protects your patient.