



I. SCOPE

This SOP details the Loyola University Medical Center (LUMC) requirements for presenting or publishing a clinical case report.

For the purposes of this SOP, a clinical case report is a narrative that describes, for scientific purposes, the symptoms, signs, diagnosis, treatment, and follow-up of a medical problem experienced by one or more patients.

II. PROCEDURES

- A. The case report author is responsible for ensuring any applicable IRB requirements are met.
- B. Case reports may be published or presented without additional internal approvals if they are fully de-identified.
 - 1. A de-identified report does not include any of the 18 HIPAA identifiers:
 - a. Name
 - b. All geographic subdivisions such as street address, city, county, precinct, zip code unless the population constitutes more than 20,000
 - c. Any dates including date of birth, admission date, discharge date, date of death. if patient is over 89, age must be aggregated into a single category of age 90 or older
 - d. Telephone numbers
 - e. Fax numbers
 - f. Electronic mail addresses
 - g. Social security numbers
 - h. Medical record numbers
 - i. Health plan beneficiary numbers
 - j. Account numbers
 - k. Certificate/license numbers
 - l. Vehicle identifiers and serial numbers, including license plate numbers
 - m. Device identifiers and serial numbers
 - n. Web Universal Resource Locators (URLs)
 - o. Internet Protocol (IP) address numbers
 - p. Biometric identifiers, including finger and voice prints
 - q. Full face photographic images and any comparable images
 - r. Any other unique identifying number, characteristic, or code.
 - 2. When assessing if a report is de-identified, the rarity of the patient's condition or presentation and the inclusion of images or pictures should be considered.
 - 3. The author may send the final draft to the Office of Organizational Integrity for review to confirm it is de-identified.
- C. The patient's HIPAA-compliant consent is required before publication or presentation if the case report will not be de-identified or if specified by the journal or publisher. The Loyola Medicine Publication Release Form may be used for this purpose.

III. REFERENCES

- A. Gagnier JJ, Kienle G, Altman DG, et al. The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development. *Glob Adv Health Med.* 2013;2(5):38–43. doi:10.7453/gahmj.2013.008
- B. 45 CFR 164.514

IV. ASSOCIATED DOCUMENTS AND FORMS

- A. Loyola Medicine Publication Release Form



V. APPROVAL


Chief Integrity Officer

11/11/2020
Date

Revision History

Effective Date	Summary of Changes
1/Jul/2019	Initial version
1/Dec/2020	Added reference to Loyola Medicine Publication Release Form