

# CASE REPORT SUBMISSION CHECKLIST

When considering what approval you need for your case study, consider the following factors. For more detail, consult [Enterprise Policy 134.04](#): Requests for and Use and Disclosures of PHI for Research Purposes.

☐ How many medical records or cases are referenced in my submission?

- For case reports involving the review of 1 or 2 medical records or cases, the researcher should complete an OHR-5 form and submit it to the Privacy Office.
  - Elizabeth David: [elizabeth.david@jefferson.edu](mailto:elizabeth.david@jefferson.edu)
  - Doreen Kornrumpf: [doreen.kornrumpf@jefferson.edu](mailto:doreen.kornrumpf@jefferson.edu)
  - Privacy Office: [privacyoffice@jefferson.edu](mailto:privacyoffice@jefferson.edu)
- For case reports involving 3 or more cases, the researcher should complete the OHR-3, OHR-4 and/or OHR-5 forms depending on whether identifiers are necessary and submit those forms to the IRB.
- A case review of three or more charts requires IRB review, as it constitutes a “systematic investigation of data for the purposes of yielding or contributing to generalizable knowledge.”

☐ Do I need patient authorization for the submission of my case report?

- If only de-identified information is included in the report, no patient authorization should be required before the researcher submits the report for publication unless the information is sufficiently “rare” as to allow for identification of the subject. The following may be helpful in determining whether this is the case:
  - How many other cases with the same or highly similar circumstances have there been at Jefferson within the past year?
  - In your professional judgment, do you believe the report can be written in such a way that the combination of details could likely not be used to uniquely identify the patient by itself or in combination with other information known to the reader?
  - If the patient’s friend or family member read the report, do you believe they would be able to identify the patient?
- Although patient authorization may not be required, the journal may require the researcher to provide a Privacy Office determination that the report reflects de-identified information.
- As such, before submitting a case report to a journal, the researcher should submit the appropriate form(s) and the case report to the Privacy Office for review.
- How do you “de-identify the data?” See page 2.

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☐ How do I de-identify the data?

- The “Safe Harbor” method includes both (A) and (B) below:

**A.** The following identifiers of the individual or relatives, employers, or household members are removed:

- (1) Names
- (2) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
  - (a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
  - (b) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
- (3) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- (4) Telephone numbers;
- (5) Vehicle identifiers and serial numbers, including license plate numbers;
- (6) Fax numbers;
- (7) Device identifiers and serial numbers;
- (8) Email addresses;
- (9) Web Universal Resource Locators (URLs);
- (10) Social security numbers;
- (11) Internet Protocol (IP) addresses;
- (12) Medical record numbers;
- (13) Biometric identifiers, including finger and voice prints;
- (14) Health plan beneficiary numbers;
- (15) Full-face photographs and any comparable images;
- (16) Account numbers;
- (17) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section “Re-identification”]; and
- (18) Certificate/license numbers.

**B.** The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

If you have additional questions or concerns, please feel free to reach out to the Privacy Office at either [privacyoffice@jefferson.edu](mailto:privacyoffice@jefferson.edu) or by phone at (215) 890-2407.