

Case Report Guidance

DEFINITIONS

Case Study/Report: “Carle Hospital is a teaching hospital that uses case studies in a variety of ways for non-research purposes. The organization of information from a patient’s medical record for a **single** case study or a case series involving data from **two or three patients** does not typically meet the definition of a *systematic investigation* and would not constitute research. This is more appropriately classified as an *education activity*. A larger case series including **four or more patients** would constitute research and would therefore need IRB approval prior to implementation.” [Carle Research Policy 111 Definition of Human Subjects Research]

Research: “Means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.” [§ 45 CFR 46.102(l)]

Protected Health Information: Protected health information (PHI) includes all individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information that was created, used, or disclosed in the course of providing a health care services (*such as diagnosis or treatment*) that can be used to identify an individual. If health information is used with any of the 18 HIPAA identifiers, it is considered PHI. For a complete list of the 18 identifiers, please refer to the last page of this guidance document.

COMMON ELEMENTS

CASE REPORT/CASE SERIES	RESEARCH
Report on one, two or three patients	Report on four or more patients
Not meant to be a representative sample (<i>not drawing conclusions</i>)	Drawing conclusions about a broader population based on the reported cases
Used as a learning tool	Used to evaluate outcomes
Reported/published without attempting to draw broader conclusions	Reported/published in a way that suggests broad findings or recommendations

FREQUENTLY ASKED QUESTIONS

Q: What is a case report or case series?

Case reports and case series typically involve the collection and presentation of detailed information about a particular patient or patients to highlight an interesting condition, treatment, presentation, or

outcome. A case report may describe a course of medical treatment for an individual patient that has a unique outcome, or the handling of a unique clinical case. A case series may contain up to three individual patients receiving similar treatment. At the time of the intervention and/or treatment, there must be no research intent or prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s).

Clinicians and medical students may have the opportunity to present unique clinical cases at professional meetings, to medical students, or to colleagues within the institution. Many case reports are also published in medical journals. Prior to presentation or publication of a case report or case series, some institutions or journals may require documentation from an IRB that IRB approval was obtained or was not required. Please contact Carle's Human Subject Protection (HSP) office if you require an official letter from Carle IRB.

Q: Do I need IRB approval if I prepare a single case report, or a case series (involving no more than 3 patients), for submission to a journal?

No. A single case report or case series involving 2-3 patients can be classified as an educational activity that does not meet the federal definition of "*research*." Therefore, the activity does not require Carle IRB review.

Q: Do I need IRB approval to use four or more clinical cases in my report?

Yes. For Carle IRB purposes, a case report or case series is a retrospective analysis of **one, two, or three** clinical cases. If four or more cases are involved in the analytical activity, the activity would meet the definition of "*systematic investigation*" and would constitute "*research*."

Q: Do I need to obtain consent from any patients about whom information will be published?

From a best practice (*and ethical*) perspective, those publishing a case report or series are strongly encouraged to obtain consent to use the patient's information, if possible. In the case of deceased individuals, consent might be obtained from the next of kin or their legal representative. NOTE: Some journals may **require** documentation of signed consent prior to publishing case reports.

Q: Are there HIPAA implications associated with a case report or case series?

Yes. Although the use of protected health information (PHI) to **prepare** the case report or series does not require IRB approval, the HIPAA Privacy Rule restricts how PHI may be **disclosed**. HIPAA requires written authorization for certain disclosures of a patient's PHI including **publication of a case report or case series**. It is the responsibility of the author to ensure compliance with patient privacy, institutional rules, and federal regulations.

If the author does not intend to include any HIPAA identifiers in the case report or series, then a signed HIPAA authorization is not required. However, prior to publishing a case report or series that **does** include HIPAA identifiers, the author must obtain a signed HIPAA authorization from the patient or patients, outlining how their PHI will be used. If a patient is deceased, a signed authorization should be obtained from the deceased patient's next of kin or legal representative. Carle's *HIPAA Authorization* template can be found in IRBNet under *Forms and Templates*. A HIPAA authorization used for a case report or series does not need to be submitted to Carle IRB for review and approval.

Q: What if the author does not intend to include any HIPAA identifiers in the case report or case series, or a signed HIPAA Authorization cannot be obtained?

If the author does not intend to include any HIPAA identifiers, or it is not possible to obtain a signed HIPAA authorization from the patient or their legal representative (if they are deceased), the patients' PHI **must** be completely de-identified before the case report is submitted to a journal or before any other type of disclosure. To de-identify the PHI, all 18 HIPAA identifiers must be removed from the case report/series (*for a complete list of the 18 HIPAA identifiers, please refer to the last page of this guidance document*).

PLEASE NOTE: One of the 18 identifiers is, “*Any other unique identifying number, characteristic, or code except the unique code assigned by the investigator to code the data.*” Often the unique characteristics that make the case report or series interesting also make it possible for others to identify the patient(s), including the patient(s) themselves. This must be considered when determining whether the case report or series can be completely de-identified. If a case is so unique that individuals with personal knowledge of the case could identify the patient, then the case report or series would not be considered de-identified and a signed HIPAA authorization would be required.

Q: Does a case report or case series write-up that will be used for teaching purposes only (e.g., presented at a conference at Carle) require a signed informed consent or HIPAA authorization?

No. If the case report or case series write-up will only be used for teaching purposes at Carle, then it is not necessary to obtain signed informed consent or a signed HIPAA authorization.

CLINICIAN ASSURANCES

- You must make every effort possible to exclude protected health information (PHI) from your case report or case series.
- If you have any question about whether the data or pictures contained in the case report or series are considered de-identified you must consult with Carle's HSP office.
- Should the information or pictures used in a case report or series be considered identifiable, you must ensure written permission is obtained from the individual or their legally authorized representative using Carle's *HIPAA Authorization* template in IRBNet under *Forms and Templates* (unless the case report/series write-up is for teaching purposes only at Carle; see last question above).

LIST OF 18 HIPAA IDENTIFIERS

1. Names (full or last name and initial)
2. All geographical identifiers smaller than a state, except for the initial three digits of a zip code if, according to the current publicly available data from the U.S. Bureau of the Census: the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 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 directly related to an individual, including birth date, admission date, discharge date, date of death; 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. Phone Numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health insurance beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers (including serial numbers and license plate numbers)
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger, retinal, and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code (this does not mean the unique code assigned by the investigator to code the data)