

Guidance on Case Reports

Case Reports are not considered research under most circumstances. Although identifiable information about a patient may be collected in preparing case reports, the intent of preparing case reports is usually related to patient care. A case report may contain information sometimes considered anecdotal in nature that discusses such areas as disease course, symptoms, response to treatment, unexpected events related to a disease process, or rare features of a disease process or response to therapy. In addition, many professional journals consider case reports to be educational in nature rather than research. Unless case reports are considered to be research, the following guidance should be applied:

- Case reports do not have to be reviewed and approved by an Institutional Review Board or a Research and Development Committee because they are not considered research.
- Educational activities are considered part of health care operations; therefore, a HIPAA authorization is not required if the information in the case report does not allow the reader to identify the person.
- Case reports should contain only de-identified information or pictures that totally conceal the identity of the individual. Note: Consultation with a Privacy Officer may be necessary to confirm that the data and pictures are de-identified. The Privacy Officer does have the authority to make this final determination.
- Written permission must be obtained from the individual if the data or the pictures are not de-identified.

There are circumstances in which case reports may be research involving human subjects. A determination whether a case report is considered research should be made by the Institutional Review Board (IRB) or a qualified individual or group of individuals. The following are circumstances when case reports may be considered research:

- The author of the case report develops a hypothesis and links other case reports to substantiate the hypotheses or to disprove the hypothesis. This activity may be similar to conducting a pilot study or a small epidemiological study. The results have become generalizable information.
- The intent is to develop generalizable information.
- It is part of a systematic effort to prove or disprove a point or some aspect of medicine or science.

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Any questions about this guidance may be addressed to the Office of Research and Development (12) or the Office of Research Oversight (10R).