***Case Reports***
***A Guidance Document***

## Purpose

This document provides guidance on when a case report requires IRB submission.

## Regulatory Guidance

The federal regulations define research as a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge (45 CFR 46.102(d))

Unless a regulatory exception applies, research involving human subjects cannot be conducted without IRB review (45 CFR 46.101 (a) and 45 CFR 46.109 (a)).

## Discussion

Case reports generally involve the collection and presentation of detailed information about a particular patient to highlight an interesting condition, treatment, presentation or outcome. There is no intent to test a hypothesis via systematic analysis, analyze data or add to generalizable knowledge. Thus, a case report that documents the clinically indicated care of a single patient does not generally meet the regulatory definition of research. The IRB is responsible for oversight of research activities. A case report that does not meet the definition of research is not subject to IRB oversight. However, a Privacy Board review still needs to occur.

A case report that only documents the observations of a patient receiving standard medical care is generally not considered research because there is no intent to test a hypothesis via a systematic data analysis. However, a case report that plans to incorporate a systematic data analysis of treatments and outcomes to allow possible extrapolation of the results to a larger population may meet the federal definition of research. Because it may meet the federal definition of research, the latter would not be considered a case report but research requiring IRB review.

When a series of patients is being reviewed, investigators usually begin to ask specific questions and systematic collection of data occurs. This moves the study closer to deriving generalizable knowledge and meeting the definition of research. The process of “testing and evaluating” the data that is generated through the patient series is what defines this activity as research. Therefore, a case series that incorporates data collection and data analysis to answer a research question must undergo IRB review.

**Conclusions**

- Do not submit case reports for publication / poster presentation involving the collection and presentation of detailed information about a particular patient to highlight an interesting condition, treatment, presentation or outcome.
- Submit for IRB review case reports that may constitute research involving human subjects:
    - Case reports/series involving **three or more** patient analysis
    - Case reports incorporating systematic data analysis
    - Case reports testing a hypothesis (e.g. Treatment A is better than Treatment B for a rare condition)
- Contact the IRB if it is unclear whether a case report should be submitted or if you would like additional assistance: irb@metrogr.org or by phone at 616-252-5020

*Other Helpful Information*

Whether IRB review is required or not, care must be taken to protect the confidentiality of the patient. Without specific written patient authorization, a case report cannot be submitted for publication if **any** of the below HIPAA identifiers are present in the manuscript (45 CFR 164.514 (b)(2)). Refer to policy COMP (HIPAA)-34 for further information on individually identifiable health information and how to de-identify.

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 a zip code if, according to the current publicly available data from the Bureau of the Census:
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. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;

11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including 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 and voice prints;
17. Full face photographic images and any comparable images;
18. Any other unique identifying number, characteristic or code

If any of these identifiers are present, written HIPAA authorization must be obtained from the patient/parent of child or if a full-face photographs or other identifying images are included (Refer to policy HIM-12). Clinical Research policy (CR-HPR-40 Case Reports) for additional guidance. If after reviewing the policy, there is a need for consent, see the attachment to the policy for the appropriate form.

It is recommended that prior to writing the case report, the authors should determine to which peer-reviewed journals the case report will be submitted. Once this has been decided, review the "Instructions for Authors" information from each journal's website. Most journals have specific requirements on publishing case reports. If the journal requires a letter from the IRB before they will publish the case report, please contact the IRB at irb@umhwest.org.

Please contact the Privacy Officer for any additional guidance: privacy@umhwest.org.