



TITLE: Mercy Case Report Authorization for Presentation/Publication	POLICY NUMBER:	S - 51
DEPARTMENT: Graduate Medical Education	Effective Date:	1/15
	Revised:	6/20
	Reviewed:	6/24
	Date of next Review:	6/26

POLICY: Case report publication must comply with HIPAA, OHRP and other applicable policies and regulations.

PURPOSE: This policy outlines the scope of what constitutes a Case Report, and the steps required to protect PHI and comply with associated regulations.

**GUIDELINES/STANDARD OPERATING PROCEDURE FOR MERCY FACILITIES:
PROCEDURE:**

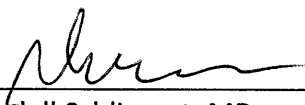
A single, retrospective case report is an activity intended to develop information to be shared for medical and educational purposes. Federal regulation (45 CFR 46.102) defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Hence, a case report of three (3) or fewer cases (with an $n \leq 3$) does not constitute human subjects research and does not require review by the IRB. A case report of one to three cases would likely not contribute or produce “generalizable knowledge” and therefore does not meet OHRP’s definition of human subjects research.

A case report or retrospective medical record review with greater than three (3) patients (an $n > 3$) would represent research and require IRB review.

The following guidelines also apply:

- Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization. Please note that in addition to removing the 18 listed HIPAA identifiers, the investigator must determine that no photo or illustration in the case report could lead to identification of the patient, and that the case(s) described are not so unique as to be identifiable with reference to other public sources such as media accounts. See appendix A for the list of 18 HIPAA identifiers that must be removed.
- Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed HIPAA compliant authorization (Appendix B). This authorization does not need to be submitted to the IRB for review.
- If the author strips off all HIPAA identifiers, but the information associated with the subject of the article includes a “unique characteristic” which would make it identifiable to the subject, or the author has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the author must contact the HIPAA Privacy Officer to discuss the required steps to take prior to publication. If in doubt, the HIPAA Privacy Officer should be consulted.

It should be kept in mind that many journals now required a patient signed case report authorization, even if not legally required. Hence, all potential case reports should strongly consider obtaining a patient or legally authorized representative's signature on a case report authorization.



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Appendix A

1. Names

2. All geographical 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:

(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 are 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. 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 (note this does not mean the unique code assigned by the investigator to code the data)

There are also additional standards and criteria to guard against re-identification. Codes used to replace the identifiers in datasets cannot be derived from information related to individuals or master codes, nor can the method to derive the codes be disclosed. For example, a subject's initials cannot be used to code associated data. Additionally, researchers must not have knowledge that the research subject could be re-identified from the remaining identifiers in the PHI. In other words, the information would still be considered identifiable if there were a way to identify the individual, even though all of the 18 identifiers were removed.



MERCY HEALTH CASE REPORT AUTHORIZATION FORM

Patient Printed Name: _____

MRN# _____ **Date of Birth:** _____

This form authorizes the use and disclosure of protected health information about the above-named patient for a case report in the form of a poster/podium presentation and/or a publication. If the case report is published, there is no payment to the patient or the authors.

A case report includes a description of the medical/surgical history in a manner that does not identify patients by name or other specific identifiers. The case report may include test results, diagnostic images such as x-rays or CT scans, or photographs of conditions such as a wound or a rash. Any information used is an existing part of the medical record. Case reports are used for educational purposes and are helpful to medical students and residents for learning.

The specific topic of this case report will be: _____

By signing this authorization:

- a. *I understand I may revoke this authorization in writing at any time. I understand the cancellation will not apply to information that has already been released/published under this authorization. Cancellation of this authorization can be achieved by sending a written revocation to the Regional HIM Manager as described in the Notice of Privacy Practices of Mercy Health Partners.*
- b. *I am not required to sign this authorization form and if I do not sign this form it will not change any medical care provided to me by Mercy Health.*
- c. *I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules.*
- d. *Any questions I have about the case report policy may be directed to the Health Information Compliance Officer at 419-696-5375 or for questions more specific to publications, please contact the Residency Academic Research office at 419-251-3842.*

Mercy Health Hospital or Mercy Physician Practice Where Services Were Provided:

Hospitals: St. Vincent St. Anne St. Charles Tiffin Willard Defiance Perrysburg St. Rita

Printed Name of Physician/Other Obtaining Authorization: _____

Signature Physician/Other Obtaining Authorization: _____ Date _____ Time _____

Mercy Practice Name if none of above: _____

Address: _____

City _____ State _____ Zip code _____

Phone: () _____

CONTINUED NEXT PAGE

Non-Mercy Healthcare Hospital or Physician/Practice Where Services Were Provided:

Printed Name of Physician/Other Obtaining Authorization: _____

Signature Physician/Other Obtaining Authorization: _____ Date _____ Time _____

Printed Hospital or Practice Name: _____

Address: _____

City: _____ State: _____ Zip code: _____

Phone: () _____

Case Report Authorization Signature

Only the patient or the LEGALLY AUTHORIZED REPRESENTATIVE (LAR) may sign this form.

The individual obtaining the signed authorization signature must personally verify the supporting documentation of legal representative authority is on file in the medical record before obtaining the signature. If supporting documentation is not in the medical record, a copy of the supporting documentation must be included with this authorization.

Patient Signature: _____

Date: _____ Time: _____ AM/PM

OR (Use for minors, legal guardian appointed etc.)

LAR Printed Name: _____

Legal Relationship to patient: _____

LAR Signature: _____

Date: _____ Time: _____ AM/PM

