



MCW Office of Research Standard Operating Procedure

CASE REPORT/CASE STUDY

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

Federal regulations define research as a systematic investigation designed to develop or contribute to generalizable knowledge. This policy describes case reports that are not generalizable and therefore do not qualify as research.

DEFINITIONS:

Case Report: a publication, article, presentation or other public dissemination of information that involves a retrospective review and description of routine medical care for a single patient. A case report has no hypothesis, no data analysis, and no generalizable conclusion.

Case Series: a group or series of case reports. This work may require IRB submission.

Case Study: a qualitative research method. It is an in-depth analysis, empirical inquiry, or investigation of a person or group in a natural, uncontrolled setting. This research method is done from the participants' perspective and studies how they make meaning of the world – not how researchers manipulate it. Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them.

A case study includes multiple data sources such as interviews, documents, archival records, direct observations, and physical artifacts. Analysis is through description, themes, and assertions. Researchers from many disciplines (e.g., social/behavioral, educational, epidemiological) use this method to build upon past theory, produce new theory, and dispute current theory.

POLICY:

A Case Report involves the description of routine medical care (standard of care) for a single patient. Case Reports may consist of publications, articles or presentations at conferences or in settings outside of the clinical, educational and research activities of MCW. Conditions, diagnoses, treatment and outcomes may be described in a Case Report. Case Reports are intended to develop information to be shared for medical or educational purposes and not to add to “generalizable knowledge.”

- A Case Report has no hypothesis, data analysis, or generalizable conclusion. As such, Case Reports do not meet the definition of human subject research as defined by the applicable institutional policies.

HIPAA requires written authorization from the patient for certain disclosures of a patient's PHI, including publication of a Case Report. Generally, the author of the Case

Report must obtain the signed authorization of the patient, or the patient's legal representative if the patient is deceased or a minor, to publish or present the information in a Case Report. HIPAA authorization may be obtained as described in *MCW Corporate SOP: Authorization for Use or Disclosure of PHI (AD.HP.080)*.

Use of PHI to prepare the publication, article, or presentation does not require HIPAA authorization.

If it is not possible to obtain authorization, the patient's PHI must be de-identified in accordance with federal regulations before the Case Report can be submitted, published, presented or disclosed in any manner.

To de-identify the PHI, 18 identifiers as described by the federal regulations must first be removed from the Case Report as described in *MCW Corporate SOP: De-identification of PHI and Limited Data Sets (AD.HP.090)*. In addition, any photographs or illustrations that could lead to identification with reference to other public sources such as media accounts must be removed from the Case Report.

As defined in the MCW Corporate SOP, one of the 18 identifiers is "Any other unique identifying number, characteristic, or code." For purposes of a Case Report, this would include a case so unique or unusual that it might be possible for others (including the patient themselves) to identify the individual(s) who is the subject of the Case Report.

In addition, HIPAA requires that at the time of publication, "[t]he 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."

PROCEDURE:

1. When clinicians identify they wish to submit a case report, clinicians should review the scope and type of work proposed to determine if IRB review and approval may be required.

Case Report:

A Case Report does not require IRB submission except in the following case:

- If a clinician considers the initiation of any additional procedures beyond what is accepted by the institution as routine care makes this activity "human subject research" requiring IRB review and approval.

Case Series:

- If the project involves 3 or less case reports, IRB submission is not required.
- If the project involves 4 or more case reports, IRB submission is required and the IRB SOP: *Submitting New Projects* should be followed.

Note: For case reports or series, some investigators may wish to receive an official letter from the IRB confirming that their project qualifies as such. Investigators seeking letters should submit a summary of their project via the eBridge "Case Report" pathway. The IRB will review the submission and provide an official letter if the project is indeed determined to be a case report / case series.

Case Study:

A Case Study requires IRB review and approval prior to the start of the project. See *IRB SOP: Submitting New Projects* for more information.

HIPAA Authorization:

1. Clinicians should review and apply the following institutional policies *MCW Corporate SOP: Case Reports Using Protected Health Information (AD.HP.240)* and *MCW*

Corporate SOP: Authorization for Use or Disclosure of PHI (AD.HP.080) to ensure the team is able to either obtain signed authorization from the patient or confirm the case report meets the definition of de-identification.

2. It is expected that either a HIPAA authorization has been obtained from the patient or their LAR prior to publication. See *MCW Corporate SOP: Authorization for Use or Disclosure of PHI (AD.HP.080)* for links to HIPAA authorization agreements.
3. If an authorization is unable to be obtained, the case report or series must be de-identified and all 18 identifiers per federal regulations and institutional policies.
4. MCW Clinicians must follow *MCW Corporate: Case Reports Using Protected Health Information (AD.HP.240)*.

REFERENCES:

45 CFR 46.160

45 CFR 46.164

SUPPORTING DOCUMENTS:

MCW Corporate SOP: Case Reports Using Protected Health Information (AD.HP.240)

MCW Corporate SOP: Authorization for Use or Disclosure of PHI (AD.HP.080)

MCW Corporate Form: Authorization to Use or Disclose Protected Health Information for Promotions, Public Relations, Publishing/Presenting or Education

IRB SOP: Submitting New Projects

Effective Date:	07/01/2023
Version number:	4.0
Previous Version/date:	3.0; 06/15/2018
Responsible Office:	HRPP Office
Approval Date:	05/29/2023

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