Marshfield Clinic

Case Reports

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.2. **Single Case Report**: The external reporting (e.g. publications or poster/verbal presentation) of an interesting clinical situation or medical condition of a single patient. Case reports normally contain detailed information about an individual patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up treatment, as well as discussion of existing relevant literature. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

2.3. **Case Series**: The external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition in a series of patients (i.e. more than one patient). Case series usually contain detailed information about each patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up treatment, as well as a discussion of existing relevant literature. The information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

2.4. **Individually Identifiable Health Information**: Health information that contains any of the following identifiers:

- Name
- Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes
- All element of dates (except year) directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health Plan beneficiary numbers
- Account numbers

- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

3. POLICY & PROCEDURE BODY

Purpose is to define a single case report as well as a case series and delineate Marshfield Clinic's position on requirements for IRB/Privacy Board approval and informed consent/authorization for each.

3.1. Background

a. There currently exists no government guidance on whether case reports fall within the definition of research. Marshfield Clinic legal opinion, confirmed by outside counsel, states that a single case report does not fall within the "Common Rule" definition of research. However, a report on a series of cases may constitute research and may require IRB review and approval as well as informed consent and privacy authorization from the subjects/patients discussed in the case series. In general, an anecdotal report on a series of patients seen in one's own practice and a comparison of these patients to existing reports in the literature is not research and would not require IRB approval. Going beyond one's own practice to seek out and report cases seen by other clinicians creates the appearance of a systematic investigation with the intent to contribute to generalizable knowledge and therefore would be considered research and would require IRB approval.

b. Legal opinion also addresses HIPAA privacy issues. HIPAA provisions governing privacy of patient information apply only if individually identifiable health information is contained within a single case report and the report is disclosed to an external entity or if a case series is determined to be research. When used or shared internally only, single case reports and case series constitute "health care operations" explicitly includes "outcomes evaluation and development of clinical guidelines" (45 CFR 164.501)

3.2. Policy

a. <u>Single Case Reports – No IRB Review Required</u>

- A single case report does not meet the federal definition of research and does not, therefore, require IRB review and approval. HIPAA provisions governing privacy of patient information only apply to a single case report if individually identifiable health information is contained within the case report and the report is disclosed to an external entity. Should any single

case report be utilized for external publication or education, or for any purpose for which patient authorization generally is required under HIPAA, the individual who will be disclosing the case must (1) either de-identify the case report by removing all individually identifiable health information or (2) obtain authorization from the subject of the case for the use and disclosure of their protected health information. The standard Marshfield Clinic authorization form should be used.

b. Case Series not Requiring IRB approval

- Case series (must meet this policy's definition of case series) that involve only individuals who are or who have been under the care of the proposed author do not meet the research definition. HIPAA provisions governing privacy of patient information apply as noted above under "Single Case Reports – No IRB Review Required"

c. Case Series Requiring IRB Approval

- A case series that does not meet this policy's definition or that involves at least one patient who is not currently or has not been under the care of the proposed author for the condition under discussion meets the definition of research and requires IRB approval as well as informed consent and authorization, unless these requirements are waived by the IRB.

3.3. Procedure

a. The prosed author of a single case report or a case series that does not meet the definition of research may proceed with development of the report in accordance with HIPAA privacy requirements stated above. No IRB review is needed.

b. The proposed author of a case series that meet the research definition, as described under the policy section above, must obtain IRB review and approval prior to development of the manuscript. Informed consent and privacy authorization are also required from each individual described in the series prior to development of the manuscript unless criteria for waiver are met, and the IRB reviews and grants a waiver.

- Most case series that require IRB review will qualify for exemption from further review but may not qualify for waiver of HIPAA privacy authorization requirements. The individual interested in preparing the series should first review the IRB Exemption Request to determine if exemption criteria are met.
  - If the proposed author is unsure if the case series will qualify for an exemption they may complete the "IRB Review Determination Request" and submit to the Office of Research Integrity & Protections (ORIP) for IRB review.
  - If exemption criteria are met, complete the IRB Exemption Request and submit to the Office of Research Integrity & Protections (ORIP) for IRB review. The criteria for waiver of authorization are contained on the same form and should be justified if a waiver is being requested.
  - IRB expedited review will be utilized to verify the exemption and determine if a waiver of authorization is appropriate.

If informed consent and authorization are required, the proposed author will receive an IRB Case Report Authorization/Consent form for their case series. The investigator must contact the subjects of the case series to obtain informed consent/authorization. If a reasonable attempt is made to locate a subject and the attempt is unsuccessful, the investigator may submit to the IRB a request for waiver of the requirement to obtain informed consent/authorization. The investigator should complete the IRB Waiver - Consent and or Authorization. An attempt to locate a subject is considered reasonable if a certified, return receipt letter is sent to the patient's last known address and the letter is returned as undeliverable. Subject/patient failure to respond to a letter that has been certified as delivered is considered indirect subject disapproval of the request to publish or otherwise use their data for the case report. The investigator is permitted to follow-up through mail, telephone, email, or other methods of communication in an effort to receive a direct response. The voluntary nature of participation must be maintained. If the subject of the project refuses to sign the consent form/authorization, the subject's information may not be used or shared for research purposes.

- The individual submitting the IRB Exemption Request will be notified of the outcome of the review.

☐ A limited number of case series will not meet exemption criteria. In this case, an IRB Application must be submitted to the IRB for review. The requirements for obtaining informed consent/authorization are the same as those noted for exempt case series.

4. ADDITIONAL RESOURCES

4.1. References:
- none

4.2. IRB Forms:
- IRB Review Determination Request
- IRB Exemption Request
- IRB Waiver – Consent and/or Authorization

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #711.3. Formatting changes. Add process of using IRB Review Determination Request form. Updated IRB Application form name.

2.0	Added hyperlink to applicable IRB Forms
3.0	Sect. 3.1 Correct typo form vs from. Sect. 3.3 Change form to request in IRB Exemption. Change IRB Waiver Consent title to match title in forms library. Add hyperlink

6. DOCUMENT PROPERTIES

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