

The Queen's Medical Center
Office of Research and Development

Policy on Clinical Case Reports and Case Series

I. Scope of Policy:

This policy provides guidance about the regulatory requirements associated with the presentation or publication of case reports.

II. Definition:

A clinical case reports is an educational activity involving a presentation or publication that documents an unusual or particularly interesting clinical phenomenon of a patient. It details the patient's history, signs, symptoms, test results, diagnosis, prognosis, treatment and clinical course of interesting clinical cases. It typically is performed by retrospective review of the medical record, contains a short literature review and discusses the importance of the case.

III. Case Reports and RIRC Review

1. Case reports (with three or fewer patients) generally do not meet the federal definition of human subjects research, as they are not designed to develop generalizable knowledge.¹ Therefore, **Research Institutional Review Committee (RIRC) approval is not required.**²⁻⁷
2. Case series (four or more patients) do meet the federal definition of human subjects research. Therefore, **RIRC approval is required.**

IV. Case Reports and HIPAA Requirements

Although case reports do not require RIRC review, they must still comply with the HIPAA Privacy Rule requirements about Protected Health Information (PHI). Authors should follow one of the following three paths prior to working on the case study.

- 1) De-identify: Authors who fully de-identify the case report do not need to obtain further authorization. *Also see System Wide Policy "Uses and Disclosures of De-Identified Health Information and Limited Data Sets, SW-21-036."*
 - a. Remove all 18 identifiers specified in the Privacy Rule (Appendix 1).⁷
 - b. Ensure that no photo, image, video or illustration can lead to identification (including PHI embedded in the file)
 - c. Ensure case described is not so unique as to be identifiable through a unique characteristic, in combination with other information, or if someone looked at public sources (e.g., media accounts)
- 2) Obtain HIPAA Authorization: Authors who cannot completely de-identify the case report should obtain a signed HIPAA compliant authorization form (Appendix 2 or download from intranet [here](#)) from the patient or legally authorized representative as appropriate (e.g., patient deceased).
 - a. This authorization form **does not need to be submitted to the RIRC but should be uploaded into the patients CareLink record** (author should ask manager, director or medical director if help is needed).
- 3) Comply with "Case Presentations" requirements in System Wide Policy "Use/Disclosure of Protected Health Information for Educational Purposes, SW-22-025."

VII. Publication Requirements

Authors who are asked by a journal or other entity to provide documentation that the case report was approved by the RIRC or did not require RIRC review may present this Policy as evidence that case reports do not require RIRC approval. Some journals may require that the institution provide written attestation that the authorization of the subject has been obtained prior to publication of the case report. To obtain this attestation, submit your case report to rirc@queens.org and a formal letter will be issued.

References

1. Basic HHS Policy for Protection of Human Subjects, 45 C.F.R. §46.101 (2018). Accessed on 5/9/23 at <https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf>
2. Sayre JW, Toklu HZ, Ye F, Mazza J, Yale S. Case Reports, Case Series - From Clinical Practice to Evidence-Based Medicine in Graduate Medical Education. *Cureus*. 2017 Aug 7;9(8):e1546. doi: 10.7759/cureus.1546. PMID: 29018643; PMCID: PMC5630458
3. Johns Hopkins Medicine. Office of Human Subjects Research, Policy 102.3 Organizational Policy on Single Case Reports and Case Series. 2023. https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_3.html
4. Boston University Medical Center. Institutional Review Board. Case Reports and Case Series. 2023. <https://www.bumc.bu.edu/irb/submission-requirements/special-submission-requirements/case-reports-and-case-series/>
5. University of Alabama. IRB Guidance for Case Reports. 2014. https://www.uab.edu/research/home/images/IRB/Guidance/Other-Guidance/IRB_Guidance_for_Case_Report.pdf
6. University of Washington. Policies, Procedures and Guidance. Guidance Case Reports, IRB Review and HIPAA. Version 1.2. 2023. <https://www.washington.edu/research/policies/guidance-case-reports-irb-review-hipaa/>
7. University of California at Irvine. Human Subject Protections. Policy #2. Case Reports. <https://research.uci.edu/human-research-protections/do-you-need-irb-review/case-reports/>
8. <https://www.hipaajournal.com/considered-phi-hipaa/>

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Appendix 1. Definition of De-Identified Data

Identifiers That Must Be Removed to Make Health Information De-Identified (2)

De-identified data are data that contain none of the 18 HIPAA identifiers. If all of the 18 identifiers are removed, the information is no longer (1) Individually identifiable, (2) PHI, and (3) subject to HIPAA's requirements

- 1) Names
- 2) Dates, except year
- 3) Telephone numbers
- 4) Geographic data
- 5) FAX numbers
- 6) Social Security numbers
- 7) Email addresses
- 8) Medical record numbers
- 9) Account numbers
- 10) Health plan beneficiary numbers
- 11) Certificate/license numbers
- 12) Vehicle identifiers and serial numbers including license plates
- 13) Web URLs
- 14) Device identifiers and serial numbers
- 15) Internet protocol addresses
- 16) Full face photos and comparable images
- 17) Biometric identifiers (i.e., retinal scan, fingerprints)
- 18) Any unique identifying number or code

Appendix 2. Authorization for Use and Disclosure of Protected Health Information



THE QUEEN'S HEALTH SYSTEMS

AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

I authorize * _____ to release the protected health information of:
 (*Facility Name)

*Patient Name: _____ Birthdate: _____

Address: _____ Phone #: _____

To: *Name or Institution: _____

Address: _____ City, State, Zip: _____

<p>*Information to be disclosed:</p> <p>Date(s) of Service: _____</p> <p><input type="checkbox"/> Discharge Summary <input type="checkbox"/> ER report</p> <p><input type="checkbox"/> History & Physical <input type="checkbox"/> Laboratory Results</p> <p><input type="checkbox"/> Consults <input type="checkbox"/> X-Ray/Imaging Reports</p> <p><input type="checkbox"/> Operative Reports <input type="checkbox"/> Entire Record</p> <p><input type="checkbox"/> Other: Please specify: _____</p>	<p>* Purposes for Use and/or Disclosure:</p> <p><input type="checkbox"/> At the request of the individual</p> <p><input type="checkbox"/> Legal Purposes</p> <p><input type="checkbox"/> Insurance</p> <p><input type="checkbox"/> Physician follow-up</p> <p><input type="checkbox"/> Other _____</p>
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_____ (initial) I agree to the release of alcohol and/or drug abuse treatment information. (If I do not specifically agree, this information will not be disclosed):

* Unless otherwise revoked, this authorization will expire on the following date or event: _____.
 If a date or event is not specified, this authorization will expire one year from my date of signature below.

This authorization is voluntary. I understand that I can refuse to sign this authorization and the facility will not condition my treatment, payment, enrollment or eligibility for benefits on the signing of this authorization except as allowed under federal privacy laws for: (i) research-related treatment; or (ii) health care provided solely for disclosure to a third party or (iii) health plan initial enrollment/eligibility determinations, underwriting or risk rating determinations.

I understand that I may revoke this authorization at any time by notifying the facility's Medical Records Department or The Queen's Health Systems' Privacy Officer, in writing, of my revocation. This is described in The Queen's Health Systems Notice of Privacy Practices. I understand that the revocation will not apply to any information that already was released in reliance on this authorization.

I understand that the health information released under this authorization may be re-disclosed by the recipient and may no longer be protected under federal privacy regulations.

I hereby release the facility from all liability and all claims of any nature whatsoever pertaining to disclosure of information, or of any professional opinions, findings, or recommendations as contained in the records released to or by the facility.

*Requestor: _____
 Signature of Patient or Authorized Representative

* _____
 Print Name

*Relationship: _____
 (Relationship to Patient) *Complete only if requestor is not patient

* _____
 Date

* Items that MUST be completed for authorization to be valid