**Writing a Case Report**

These guidelines include information from Carilion Clinic’s Privacy Office that includes important details around access, use and disclosure of a patients protected health information when performing a case report. These guidelines for writing a case report will be helpful for anyone writing case reports. Prior to contacting the patient or entering the patient’s medical record whose case you want to write about **you must contact the physician of record to obtain permission to proceed with the case report.**

**What is a case report?**A case report is the external reporting (publication, poster presentation, verbal presentation, etc.) of an interesting clinical situation or medical condition of a single patient or a series of patients (involving three or fewer patients). Case reports normally contain detailed information about patient(s) and may include demographic information, information on diagnosis, treatment, response to treatment, etc. A case report involving three or less patients does *not* *require* Institutional Review Board approval, however, it is important to consider the requirements of the publisher. Many publishers *require* a “Not Human Subject Research Determination” Letter from the applicable Institutional Review Board. The Carilion Clinic Institutional Review Board does *not* issue retrospective determination letters. To obtain a “Not Human Subject Determination” Letter from the Carilion Clinic IRB you must submit a Determination of Human Subjects Research application with PRIS3M. PRIS3M can be accessed at <https://carilionclinic.imedris.net/> using your Carilion Clinic username and password. For additional help on submitting this application please reach out to the Carilion Clinic IRB at irb@carilionclinic.org.

An important thing to note is regardless of any “Not Human Subject Research Determination,” Carilion Clinic Privacy Policies still apply. According to Carilion Clinic Policy, staff must meet one of the two requirements to directly access PHI for the purposes of a case report:

1. Be directly involved in the patient’s care either currently or in the recent past.
2. Formally assigned the education/academic task of a case study requiring direct access to patients’ charts which encompasses the following learner roles:
	1. Members of medical staff
		1. Examples include physicians, dentists, pharmacists, physician assistants, nurse practitioners, nurse anesthetists, registered nurses, and licensed social workers.
	2. Residents and fellows
	3. Students who are approved for a formal rotation at Carilion Clinic.

**Case reports are commonly of the following categories**:

* Rare diseases
* Unusual presentation of disease
* Unexpected events
* Unusual combination of diseases or conditions
* Difficult or inconclusive diagnosis
* Treatment or management challenges
* Personal impact
* Observations that shed new light on a disease or condition
* Anatomical variations

It is important that you described clearly in the case report what is unique or interesting about your case.

**Case reports take the format of**:

1. Background

2. Case presentation

3. Observations and investigation

4. Diagnosis

5. Treatment

6. Outcome

7. Discussion

Variations of case reports found in a variety of journals including the following:

* 1. Letter to editor
	2. Clinical-Pathologic Correlation
	3. Clinical Image
	4. Teaching case

**How do I begin writing a case report?**

1. You are encouraged to consult the CARE Guidelines, which provide guidance on writing case reports - <https://www.care-statement.org/> .Specifically, the checklist - <https://www.care-statement.org/checklist> - which explains exactly the information you should collect and include in your case report.

2. How to identify a case. If you are a medical student, you may not yet have the clinical expertise to determine if a specific case is worth writing up. If so, **you must seek the help of the clinician that took care of the patient.** Students commonly ask attendings or residents if they have any interesting cases that would be appropriate for a case report. However, the clinician taking care of the patient must be contacted before accessing the medical record as the student will be collecting protected health information, thus HIPAA applies to case reports.

3. Select a journal or two to which you think you will submit the case report. Journals often have specific requirements for publishing case reports, which could include a requirement for informed consent, a letter or statement from the IRB and other things. Journals may also charge publication fees (see **Is it free to publish?** below).

4. The physician of record should obtain informed consent from the patient and include any physician or provider with direct involvement in the care of a patient with signed notes or reports in the medical record. Journals may have their own informed consent form that they would like you to use, so please look for this when selecting a journal.

Once a case has been identified, informed consent obtained, and an appropriate journal selected, then collection of the required information can occur to write the case report.

**Do I have to obtain informed consent from the patient?**

It is the recommendation of the Carilion Clinic Privacy Office to obtain written authorization from the patient or their legally authorized representative to use their protected health information (PHI) for educational purposes, which includes case reports. The **Patient Authorization to Use and Disclose Protected Health Information for Education/Academic Purposes (attached)** can be found on **Inside Carilion’s Document Center.** PHI cannot be used or disclosed for purposes of a case report until the PHI Authorization for Education/Academic Purposes is signed by the patient. The authorization must then be sent to Carilion Clinic’s HIM department for processing via interoffice mail. Proceeding with a case report *without* authorization from the patient is *only* permitted if all 18 HIPAA identifiers are removed. It is important to acknowledge that any other unique identifying number, characteristic or code could result in the information being not fully de-identified, which is a common occurrence for case studies. There are two ways to de-identify PHI, one is by meeting the safe-harbor requirements which includes removing all 18 HIPAA identifiers, and the other is by an expert determination. Due to the often-rare conditions discussed in case studies, and if consent cannot/will not be obtained, it is the Privacy Office’s recommendation to utilize de-identification by expert determination to ensure proper de-identification. The clinical staff member who meets the above-listed requirements must reach out to the Carilion Clinic Health Analytics team to request de-identification of PHI by expert determination. The Health Analytics team could determine that the PHI cannot be fully de-identified, thus requiring written consent from the patient. The Carilion Clinic Privacy Office should be contacted at privacy@carilionclinic.org for all planned external access, use and disclosure of de-identified patient information.

An additional consideration is the requirements of the publisher. Some require consent from the patient before publishing articles, even if de-identified data is being used. The Carilion Clinic Privacy Office is a committed resource to staff, students, and patients. If you have any questions or request additional guidance please reach out to privacy@carilionclinic.org or researchcompliance@carilionclinic.org.

**Seek feedback**

Once you have written a draft of the case report, you should seek feedback on your writing, from experts in the field if possible, or from those who have written case reports before.

**Is it free to publish**?

Be aware that it may not be free to publish your case report. Some journals charge publication fees. Of note, many open access journals charge author fees of thousands of dollars. Other journals have smaller page charges (i.e., $60 per page), and still others will publish for free, with an "open access option". It is best practice to check the journal's Information for Authors section or Author Center to determine what the cost is to publish. Carilion and/or Virginia Tech may have funds to support publication costs, so this is an important step if you do not want to pay out of pocket for publishing.

**References:**

* *Policies on Inside Carilion PageCenterX Systemwide:* Access to Protected Health Information for Education Purposes, Deidentifying Protected Health Information
* Document Center on Inside Carilion: Patient Authorization to Use and Disclose Protected Health Information for Education/Academic Purposes
* 45 C.F.R. Parts 160 and 164, as amended by the Privacy and Security Provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public Law 11-5 (“HITECH Act) and the rules promulgated thereunder (collectively referred to herein as the “HIPAA Rules”).
* Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D. 2013. The CARE guidelines: Consensus-based clinical case reporting guideline development. *Glob Adv Health Med*. 2:38-43. doi: [10.7453/gahmj.2013.008](https://dx.doi.org/10.7453/gahmj.2013.008)
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