**Northern NSW Local Health District template for case study/series**

Version 6 January 2023

**What is a case study/series?**

A case study or report can be considered the detailed presentation of the clinical description and findings of a patient based on a hospital stay, episode of care or healthcare journey for a health condition or problem. The report itself will comprise entirely of information and data gathered during routine (standard) care delivered to a patient. A case series presents the same type of information as a case study, but for several patients.

**Ethical considerations, health information privacy principles and governance for case study/series**

As case study/series propose to use existing personal health information obtained during standard care, they are classed as negligible risk and qualify for exemption from ethical review in accordance with section 5.1.22 of the [*National Statement on Ethical Conduct in Human Research (2007)*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018). However, as they involve the detailed presentation of the clinical characteristics and healthcare journey of one or several patients, it’s quite possible that anyone familiar with the patients may identify them from reports even when only de-identified data are presented. Therefore, as per the [Statutory Guidelines on Research](https://www.ipc.nsw.gov.au/sites/default/files/2019-01/statutory_guidelines_on_research.pdf) for the *Health Records and Information Privacy Act 2002* (NSW), explicit, informed consent is required from patients that are the subject of a case study or case series. The minimum governance requirement for a case study/series involves obtaining support for the activity from a relevant Head of Department / line manager. Email evidence of this support suffices for the application.

**Instructions for completing and submitting a case study/series application for review by the Research Office, Northern NSW Local Health District (NNSWLHD)**

To submit an application for a case study for consideration by the NNSWLHD Research Office, please complete the following:

* Template at **Appendix 1** to detail the background and rationale for the case study/series, whether it is intended that the report be submitted for publication and/or presented and how data for the study will be accessed and stored.
* Adapt the template at **Appendix 2** to obtain explicit, informed consent from the patient. The template needs to be adapted to contain the information for the Coordinating Principal Investigator and their clinical unit/department. Once the template is endorsed by the Research Office consent may be sought. Submit the signed copy to the Research Office before final approval may be issued.
* Adapt the template at **Appendix 3** for revocation of consent, which provides a formal mechanism for a patient to withdraw from a study at any time should they wish. Once the template is endorsed by the Research Office consent may be sought. If the patient later revokes consent, please notify the Research Office, NNSWLHD.
* Submit all completed documentation (including evidence of Head of Department / line manager support) to NNSWLHD-Ethics@health.nsw.gov.au.

Please complete documents electronically (hand-written forms will not be accepted).

**Northern NSW Local Health District template for case study/series**

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| **Project title:** | *Use a descriptive, informative title that succinctly describes the study including the main project idea, study site, and the study design.* |
| **Coordinating Principal Investigator:**  | *Full name and title.* |
| **Position:** |  |
| **Department and Facility:** |  |
| **Employee Number:** |  |
| **Email:** |  |
| **Phone:** |  |

***Background and rationale for the case study/series***

*One or two paragraphs summarising why this case is unique and important to report (may include references)*

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***Indicate where you plan to disseminate the findings of your case study/series:***

C*heck all that apply and provide details as appropriate*

[ ] Internal report: Please provide details

[ ] External report: Please provide details

[ ]  Presentation: Please provide details e.g. unit, department, scientific conference

[ ]  Publish in a peer-reviewed journal: Please provide details

[ ]  Other: Please provide details

Please note: If you intend to publish the findings of your case study/series please refer to:

* Gagnier JJ, Kienle G, Altman DG*, et al* [The CARE guidelines](https://casereports.bmj.com/content/casereports/2013/bcr-2013-201554.full.pdf): consensus-based clinical case reporting guideline development. *Case Reports* 2013;**2013:**bcr2013201554.
* [CARE checklist of information to include when writing a case report](https://static1.squarespace.com/static/5db7b349364ff063a6c58ab8/t/5db7bf175f869e5812fd4293/1572323098501/CARE-checklist-English-2013.pdf).

***Provide information on the data required and the data source for the study***

*Data required e.g. patient’s demographic details, diagnostic tests and treatment provided. Data source e.g. clinical information system(s) that will be used to obtain the data.*

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***Describe how patient information will be deidentified, stored and utilised to maintain confidentiality***

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***[Please send completed form to*** ***NNSWLHD-Ethics@health.nsw.gov.au******]***

**PATIENT CONSENT FORM – CLINICAL CASE STUDY/SERIES**

**Patient’s name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project title**: Project title.

**Details of the Coordinating Principal Investigator:**

**Name**: Name of the Coordinating Principal Investigator

**Phone**: Click or tap here to enter text. **Email**: Click or tap here to enter text

**Mailing address**: Click or tap here to enter text.

* I, .............................................................................................. *[patient full name]* consent to participating in this case study/series, and understand that my personal health information relevant to this study may appear in a scientific journal, report or other similar publication, and/or in a presentation at a health and medical research conference(s).

In giving my consent, I confirm that:

* I have been fully briefed of my involvement in this project, its purpose, potential risks, and intended uses/benefits, and I have been given the opportunity to ask any questions relating to any possible physical and/or mental risks I might be exposed to as a result of participating in this study.
* I permit only de-identified information be published (i.e. without my name attached), and I understand the investigators will make every attempt to ensure my anonymity. I also understand that complete anonymity cannot be guaranteed, and it is still possible that somebody familiar with me (e.g. staff who looked after me in hospital or a relative) may identify me.
* If the study is to be published, I will be informed in which journal the research and my information will be published in, its audience (e.g. mostly doctors or a broader readership) and reach (e.g. published in local journal or international journal).
* I can revoke my consent at any time before publication without prejudice to my relationship with the Coordinating Principal Investigator, doctors and staff responsible for my treatment, and anyone else at specify the department, hospital/facility.
* I understand that if I have any questions relating to my participation in this research, I may contact Insert the name of the Coordinating Principal Investigator.
* I have a copy of this Consent Form to keep.

Any feedback or concerns about the conduct of this activity may be directed to the Research Office, Northern NSW Local Health District by emailing NNSWLHD-Ethics@health.nsw.gov.au or telephone (02) 6672 0269

**Participant**

Signature: Print name: Date:

**Coordinating Principal Investigator**

Signature: Print name: Date:

**REVOCATION OF CONSENT FOR CLINICAL CASE STUDY/SERIES**

**Project title**: Project title.

I hereby wish to **WITHDRAW** from the project described above and understand that such withdrawal **WILL NOT** affect my relationship with the Coordinating Principal Investigator, doctors and staff involved in my health care or anyone else at the specify the department, hospital/facility, Northern NSW Local Health District.

Signature Date

Please PRINT Name

Please forward the Revocation of Consent to (please retain a copy):

**Details of the Coordinating Principal Investigator:**

**Name**: Name of the Coordinating Principal Investigator

**Phone**: Click or tap here to enter text. **Email**: Click or tap here to enter text

**Mailing address**: Click or tap here to enter text.

If revocation of consent is communicated verbally to the Coordinating Principal Investigator, please sign and date below:

Coordinating principal investigator signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date revocation of consent received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please send completed revocation of consent to:*** *NNSWLHD-Ethics@health.nsw.gov.au*