Northern NSW Local Health District template for case studies/series

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 a small group of patients.

Ethical considerations, health information privacy principles and governance for case studies

As case studies 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. However, as they involve the detailed presentation of the clinical characteristics and healthcare journey of a single patient (or small group of patients for a case series), 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 for the Health Records and Information Privacy Act 2002 (NSW), explicit, informed consent is required from patients that are the subject of case studies. The minimum governance requirement for a case study 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 application for review by the Research Office

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

- A cover letter detailing the background and rationale for the case report/study, 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 (template provided at **Appendix 1**).

- 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 investigator and their clinical unit/department. Once consent is obtained, a copy is to be submitted to the Research Office for final authorisation.

- 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.

- Submit all completed documentation to NNSWLHD-Ethics@health.nsw.gov.au.

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

Coordinating Principal Investigator
Title & name:
Department:
Position:
Contact email:

Dear North Coast NSW Human Research Ethics Committee Executive Officer,

RE: Case report – Request for review

Background and rationale for case the study

Indicate whether you intend to publish and/or present the report

Please provide information on the data to be accessed (e.g. data sources, clinical information systems)

Please state how information will be stored and utilised to maintain confidentiality

Yours sincerely,

Coordinating Investigator

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

Health
Northern NSW
Local Health District

PATIENT CONSENT FORM – CLINICAL CASE REPORT

Name of patient participating in the study: _____

Project title: _____

Coordinating investigator: _____

Co-investigators: _____

- I, ... *[patient full name]* consent to participating in this case report/study, 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.
- Only de-identified information will be published (i.e. without my name attached), and the investigators will make every attempt to ensure my anonymity. However, I 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 researchers, doctors and staff responsible for my treatment, and anyone else at [Department, hospital/facility]
- I understand that if I have any questions relating to my participation in this research, I may contact [insert contact details]
- I acknowledge receipt of a copy of this Consent Form.

Complaints may be directed to the Northern NSW Local Health District Human Research Ethics Committee by emailing NNSWLHD-Ethics@health.nsw.gov.au or telephone 02 6672 0269

Participant
Signature: Print name: Date:

Coordinating Investigator
Signature: Print name: Date:

REVOCATION OF CONSENT FOR CLINICAL CASE REPORT

I hereby wish to **WITHDRAW** from the study described above and understand that such withdrawal **WILL NOT** affect my relationship with the researchers, doctors and staff involved in my health care or anyone else at the [department, hospital/facility]

Signature Date

Please PRINT Name

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

Coordinating Investigator details