RESPONSIBLE EXECUTIVE	Angela Watt
PRIMARY AUTHOR	Sarah Rickard
IMPLEMENTATION STRATEGY	Email update to all employees and uploaded to the Office for Research website.
EVALUATION STRATEGY	Updated policy to be evaluated by Melbourne Heal (MH) the Office for Research Ethics and Governance management teams.
STANDARD/S (National, Aged Care, Disability Services)	NSQHS Clinical Governance Standard.
VERSION SUMMARY	These guidelines have been developed to set out the requirements for publication of Case Studies by MH staff. They define the responsibilities of authors, Heads of Departments and the Human Research Ethics Committee (HREC), requirement of consent, when HREC review and approval is required, removing identifying information and publishing the information.

EXECUTIVE SUMMARY

1. A case report is description and explanation of an individual patient's medical diagnosis and treatment, considered to be of educational value for other health professionals. It is not a research project.
2. Written consent should be obtained from the patient who is the subject of the case study, if it is reasonably practicable.
3. Where patient consent to use/disclose the patient's information in the Case Study/Series Report is not possible, a waiver of consent must be obtained from the MH Human Research Ethics Committee (HREC) to use the information.
4. If the patient does not consent, or the HREC does not give approval of a waiver of consent, the case must not be published.
5. All identifiable features must be removed from the Case Study/Series Report and the manuscript should only contain those features that are necessary to communicate the patient's particular clinical situation and should, wherever possible, generalise features.
6. Publication of case study information must be in accordance with the Australian Code for the Responsible Conduct of Research (2018) and its accompanying guide documents, MH requirements and must not impinge on the integrity of research study or clinical trial data that the patient may be involved in.
7. The lead authors Head of Unit/Department is responsible for acknowledging patient consent and approving the manuscript.

1. ASSOCIATED MELBOURNE HEALTH POLICY

Melbourne Health Research Policy MH 18

2. PURPOSE AND SCOPE

The Guidelines for Publication of Case Study Report have been developed to clearly set out the roles and responsibilities of MH and its Human Research Ethics Committee (HREC) and the processes in place in relation to the publication/dissemination of case study reports about MH patients (individual cases and case series) in medical journals, theses or external presentations.

The purpose of the Guidelines is to provide general principles to guide authors who want to write up a case study report on a MH patient and present or submit this for publication.

These guidelines have been written in accordance with the National Statement on Ethical Conduct in Human Research (2018) and the Australian Code for the Responsible Conduct of Research (2018).

3. DEFINITIONS

Case Study Report	A description and explanation of an individual patient's medical diagnosis and treatment, considered to be of educational value for other health professionals. The 'case' is often distinctive in some way (e.g. the manifestation of an unusual

	or rare disease) and this increases the potential that an individual patient could be identifiable.
Case Series Report	A description and explanation of the medical diagnoses and treatment of a series of patients or cases. This could include demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment. As more than one patient is involved, this may lessen the potential for individual patients to be identified. The point at which a series of case studies becomes a Case Series Report is the point at which the individuals' identities are merged, so that, to the greatest extent possible, no individual is identifiable from amongst the Case Series.

4. RESPONSIBILITIES

The MH Office for Research will keep a register of publications and authors.

It is the responsibility of researchers to disseminate research findings responsibly, accurately and broadly.

Clinicians, researchers and Heads of Units/Departments should be aware of and abide by these guidelines for case reports.

4.1 AUTHOR

The author is often, but not always, the health professional that had primary medical responsibility for the patient/s described.

The author is responsible for:

- adherence to MH guidelines, including this guideline, policy, and other applicable requirements
- obtaining all required approvals including Head of Department approval, HREC approval if requiring a waiver of consent
- obtaining and recording the relevant consent
- ensuring de-identification of data and images in the manuscript
- abiding by journal requirements

4.2 HEAD OF UNIT/DEPARTMENT:

The lead authors Head of Unit/Department is responsible for:

- approving the manuscript
- checking that the report does not involve unacceptable risk to MH or patient/s
- ensuring appropriate communication has taken place with the relevant medical staff

Note: If the lead author is non-medical, then the Head of Unit/Department of the clinical team which provides overarching care to the patient must approve the manuscript.

4.3 MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE (MH HREC)

The MH HREC is responsible for:

- reviewing requests for a waiver of consent to use/disclose information where it is not possible to obtain patient consent to use/disclose the information in the Case Study /Series Report.
- assessing the request in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated 2018) and the Statutory Guidelines on Research issued under the Health Records Act 2001 (Vic).

5. PROCEDURE/GUIDELINE/POLICY

5.1. INTRODUCTION

MH is committed to promoting an environment of honesty, integrity and accuracy in reporting and publishing.

Case Study/Series Reports are descriptive and have a particular format. They differ from research activities, such as medical record 'audits', which use already-collected health information and are not subject to the same ethical review requirements as research involving MH patients.

'These guidelines should be read in conjunction MH and the Office for Research policy and guidelines.

These guidelines have been developed in accordance with:

- National Statement on Ethical Conduct in Human Research (2007updated 2018) (National Statement)
- Authorship - A guide supporting the Australian Code for the Responsible Conduct of Research (2019)

5.2. **CONSENT**

5.3.1 Written consent should be obtained from the patient who is the subject of the case study, if it is reasonably practicable, for individual Case Study Reports.

5.3.2 For Case Series Reports, written consent from each patient is not mandatory unless the subject matter is particularly sensitive, or it is considered likely that an individual could be identified. However, if patients in a series of cases remain individually identifiable in a report, then the consent requirements for an individual Case Study Report should be followed for each patient/case.

5.3.3 Where it is not reasonably practicable to contact the patient for consent (for example, if the patient lacks the capacity to consent and is not likely to regain capacity in the short term, or if the patient is deceased), approval for a waiver of consent must be obtained from the MH HREC.

5.3.4 Consent cannot be provided by a Medical Treatment Decision Maker (or other family member) on a patient's behalf as use and disclosure (including publication of data) does not come under the Medical Treatment Planning and Decisions Act 2016 (VIC).

5.3.5 If the patient does not consent, or the MH HREC does not give approval of a waiver of consent, the case must not be published.

5.3.6 Consent form:

- Use the MH Consent for Publication of Case Study Report form in Appendix 1, OR other appropriate MH approved consent form that includes/has an option for consent for research and publication i.e. Clinical Photography and Video consent form".
- A MH consent form must be used, whether or not the journal has its own.
- Note that some journals mandate the use of their own consent form and require the author to submit the signed original.

5.3. **WHEN HREC REVIEW AND APPROVAL is REQUIRED**

HREC review and approval **is required:**

- when it is not reasonably practicable to contact the patient for consent (for example, if the patient lacks the capacity to consent and is not likely to regain capacity in the short term, or if the patient is deceased) and a waiver of consent is requested.

The HREC should also be consulted, and may need to review the proposed report, if the case raises particular ethical issues (e.g. if the subject matter of the report is particularly sensitive).

HREC review **is not** required if ALL the following apply:

- the patient has provided written consent
- the report does not contain identifying information
- the publication of the report involves negligible risk to the patient, others who might be affected (e.g. a specific cohort) or the organisation.

Applying for a waiver of consent:

Submit 'application by letter' to the MH HREC outlining the request and include:

- name and department of the lead author
- request for a waiver of consent to use a patient information without their consent
- justification of the waiver of consent by addressing the criteria in the National Statement on Ethical Conduct in Human Research, Chapter 2.3: 'Qualifying or waiving conditions for consent', Section 2.3.10.

Submit the 'application by letter' to the MH Office for Research via email at research@mh.org.au.

Note: a letter from the HREC, confirming that the activity is exempt from ethical review, can be provided if a journal requires this. Send requests to the MH Office for Research via email at research@mh.org.au.

5.4. REMOVING IDENTIFYING INFORMATION

All identifiable features must be removed from the Case Study/Series Report.

The manuscript should only contain those features that are necessary to communicate the patient's particular clinical situation and should, wherever possible, generalise features.

De-identify the case to the greatest extent possible, by:

- not using names, dates-of-birth, postcodes, identifying aspects of images
- generalising details (e.g. use age range rather than age)
- including only details that are clinically and scientifically relevant, and essential to understanding and interpreting the case (e.g. socio-demographics, race/ethnicity, etc.)
- removing any non-essential characteristics/information

Where the patient has not consented, special care must be taken by the author to thoroughly de-identify the case.

5.5. RESPONSIBLE PUBLISHING

'Publication' pertains primarily to medical journals, but also to publicly-available theses, abstracts and external presentations (e.g. conferences).

Many journals have specific requirements for Case Study/Series Reports and authors are advised to check the publication policy of relevant journals before writing their manuscript.

It is essential that anyone intending to publish a case report checks that the publication:

- will not result in a breach of the Australian Code for the Responsible Conduct of Research (2018) and its accompanying guide documents
- impinge on the integrity of research study or clinical trial data that the patient may be involved in.

For research study / clinical trial participants - where a case report involves a patient on a clinical trial, or any other research project, potential authors must:

- check that publication of the case report will not constitute an inappropriate disclosure of research data and/or source materials, or breach of agreement.
- consult with Principal Investigators and research sponsors before publication of case reports involving research/trial participants.

5.6. **Head of Department / Divisional Director SIGNOFF OF CASE STUDIES**

- The Head of Unit/Department must sign the acknowledgement section of each consent form.
- The Head of Unit/ Department must approve the manuscript before it is submitted for publication.
- Where the Head of Unit/ Department is the Requesting Author, the Divisional Director should sign the consent form acknowledgement and approve the manuscript.

6. ASSOCIATED POLICIES/PROCEDURES/GUIDELINES

- MH Research Policy MH18
- Documentation and Records Management MH 05
- Research Publications and Authorship Guideline
- Data Management in Research Guideline
- Data Storage and Security Guideline

7. REFERENCES

- Australian Code for the Responsible Conduct of Research (2018)
- Authorship - A guide supporting the Australian Code for the Responsible Conduct of Research
- National Statement on Ethical Conduct in Human Research (2007updated 2018)
- Ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples (NHMRC)
- Guidelines for Ethical Research in Australian Indigenous Studies (AIATSIS)

8. FURTHER INFORMATION

Contact the Office of the Office for Research on 9342 8530 or email: research@mh.org.au

9. DOCUMENTATION

- Consent For Publication Of Case Study Report form (Appendix 1)

10. REVISION AND APPROVAL HISTORY

Date	Version	Author* and contributors
10/01/2019	1	Jessica Turner, Manager, Melbourne Health Human Research Ethics Committee
23/05/2019	2	Jessica Turner, Manager, Melbourne Health Human Research Ethics Committee
12/5/2020	3	Sarah Rickard, Manager of Research Governance and Audit
25/8/2020	4	Sarah Rickard, Manager of Research Governance and Audit • Update 5.3.6 to include use of other appropriate MH approved consent form that include/have an option for consent for research and publication i.e. Clinical Photography and Video consent form".
28/8/2020	5	Sarah Rickard, Manager of Research Governance and Audit • Update Version summary to reflect current content.

Acknowledgement: MH would like to acknowledge the Alfred Health's Publication of Case Study Reports Guidelines in the development of this document.

APPENDIX 1

CONSENT FOR PUBLICATION OF CASE STUDY REPORT

[Please replace blue italicized text with the relevant information and also remove this instruction].

What is a Case Study Report?

A Case Study Report is a description and explanation of an individual patient's medical diagnosis and treatment, considered to be of educational value for other health professionals. Reports are intended to be published or presented in forums aimed mainly at health care professionals (e.g. in a medical journal, thesis, or at a conference), although they are usually publicly available.

What is this Case Study Report about?
[Briefly describe content, images.]

Where could this Case Study Report be published?
[If known, include details - e.g. name of journal, title of article, forum of presentation]

Will people who read the Case Study Report know who it is about?

The report will be published without the name of any patient and every attempt will be made not to include details that could identify who the report is about. However, complete anonymity cannot be guaranteed. It is possible that somebody somewhere - perhaps, for example, somebody who looked after you in hospital - may identify you.

Can you change your mind?

You can withdraw your consent at any time before the manuscript has been committed to publication, but thereafter it will not be possible to withdraw your consent.

CONSENT FOR PUBLICATION OF CASE STUDY REPORT

CONSENT

I _____ [name of patient]

consent for information about me relating to the subject matter above, to be published in a journal article, or to be used for the purpose of a thesis or presentation.

Signature of patient: _____ Date: ….. / ….. / …..

Requesting Author:

Print Name _____

Signature _____ Date ….. / ….. / …..

Acknowledgement by Head of Department / Divisional Director
(*Divisional Director to sign where Head of Department is the Requesting Author*):

Print Name _____

Signature _____ Date ….. / ….. / …..

Department/Unit _____

**Please note:*

- *Consent cannot be provided by a Medical Treatment Decision Maker (or other family member) on a patient's behalf as use and disclosure (including publication of data) does not come under the Medical Treatment Planning and Decisions Act 2016 (Vic).*
- *In the event that the patient(s) concerned is not capable/competent to provide written informed consent for themselves, or if the patient is deceased, an application must be made in writing to the MH Human Research Ethics Committee requesting approval of a waiver of the requirement for informed consent.*
- *Requests for approval of a waiver of consent must be made in accordance with the Health Records Act 2001 (Vic) (see Victorian Specific Module section 2 for guidance about information to provide to HREC as justification for the request to waive requirement for consent:* https://www.thermh.org.au/research/researchers/ethics.