<table>
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<tr>
<th>NAME OF DEPARTMENT</th>
<th>OFFICE FOR RESEARCH</th>
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<tbody>
<tr>
<td>NAME OF DOCUMENT</td>
<td>Publication of Case Study/Series Reports</td>
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<tr>
<td>ASSOCIATED MELBOURNE HEALTH POLICY</td>
<td>Research Policy</td>
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<tr>
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<td>23 May 2019</td>
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<td>FUNCTIONAL GROUP</td>
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<td>DIVISIONAL SPONSOR</td>
<td>Director, Research Governance and Ethics</td>
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<td>EQUIP CRITERIA</td>
<td>Standard 15 – Corporate Systems and Safety.</td>
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<td>Criterion 15.4 – The organisation’s research program develops the body of knowledge, protects staff and consumers/patients and has processes to appropriately manage the organizational risk</td>
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<td>SUMMARY</td>
<td>The Guidelines for Publication of Case Study Report have been developed to clearly set out the roles and responsibilities of Melbourne Health (MH) and its Human Research Ethics Committee (HREC) and the processes in place in relation to the publication/dissemination of case study reports about Melbourne Health patients (individual cases and case series) in medical journals, theses or external presentations. 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). These guidelines should be read in conjunction with the MH Guidelines for Research Practice.</td>
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1. ASSOCIATED POLICY
MH Research Policy

2. PURPOSE AND SCOPE
Authorised by: Executive Director of Research
The Guidelines for Publication of Case Study Report have been developed to clearly set out the roles and responsibilities of Melbourne Health (MH) and its Human Research Ethics Committee (HREC) and the processes in place in relation to the publication/dissemination of case study reports about Melbourne Health 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 Melbourne Health patient and present or submit this for publication.

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. GUIDELINE

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 Melbourne Health patients.

‘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.

The role and responsibility of relevant parties

Those with particular responsibilities are:

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 obtaining and recording the relevant consent/consent waiver, ensuring de-identification of data and images in the manuscript, and abiding by journal requirements. The author bears primary responsibility for adherence to this Guideline.

Head of Unit/Department:
The Head of Unit/Department is responsible for approving the manuscript checking that the report does not involve unacceptable risk to Melbourne Health, and that appropriate communication has taken place with the relevant medical staff. Where there is more than one author, then the lead author’s Head of Unit/Department must approve. 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.

Melbourne Health Human Research Ethics Committee:
In cases where it is not possible to obtain consent from the patient to use/disclose the patient’s information in the Case Study/Series Report, the Ethics Committee may give approval. This assessment would be made in accordance with the National Statement on Ethical Conduct in Human Research and the Statutory Guidelines on Research issued under the Health Records Act 2001 (Vic). The Ethics Committee 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).

General principles

- 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.
- 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. 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.
- 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), consent may be obtained from the patient's medical treatment decision maker.
- If the patient (or medical treatment decision maker) does not consent as it is not reasonably practicable to contact the patient (or medical treatment decision maker) for consent approval must be obtained from the Melbourne Health Human Research Ethics Committee. Where review or input from the Ethics Committee is required, an ‘application by letter’ should be submitted to the Office for Research (via email at research@mh.org.au). If a consent waiver is being requested, the applicant should address 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.
- If the patient (or medical treatment decision maker) does not consent, or the Ethics Committee does not give approval, the case must not be published.
- All identifiable features must be removed from the Case Study/Series Report. (See “Removing identifying information” below.) The manuscript should only contain those features that are necessary to communicate the patient’s particular clinical situation and should, wherever possible, generalise features (for example by giving an age range rather than a specific age). Where the patient has not consented, special care must be taken by the author to thoroughly de-identify the case.
- Responsible Conduct of Research: 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. Where a case report involves a patient on a clinical trial, or any other research project, potential authors must first check that publication of the case report will not constitute an inappropriate disclosure of research data and/or source materials. Authors are obliged to consult with Principal Investigators and research sponsors before publication of case reports involving research/trial participants.

Applying general principles

Consent

- Written consent should be obtained using the Melbourne Health Consent for Publication of Case Study Report (Appendix 1). This 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.

Removing identifying information

- Authors should 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

**Review/sign-off**

- The head of unit or department must approve the manuscript before it is submitted for publication.
- Ethics Committee review is not required if all of 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 or others who might be affected (e.g. a specific cohort)

A letter from the Ethics Committee, confirming that the activity is exempt from ethical review, can be provided if a journal requires this.

5. **FURTHER INFORMATION**

   Contact the Office for Research on (03) 9342 8530.

6. **REVISION AND APPROVAL HISTORY**

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<th>Date</th>
<th>Rev No</th>
<th>Author and approval</th>
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<tr>
<td>10/01/2019</td>
<td>1</td>
<td>Jessica Turner, Manager, Melbourne Health Human Research Ethics Committee</td>
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<tr>
<td>23/05/2019</td>
<td>2</td>
<td>Jessica Turner, Manager, Melbourne Health Human Research Ethics Committee</td>
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Disclaimer: This guideline has been developed based on the Alfred Health Publication of Case Study Reports Guidelines.
APPENDIX 1

CONSENT FOR PUBLICATION OF CASE STUDY REPORT

[Please replace blue italicized text with the relevant information and also remove this instruction] Note that this consent may be amended to also be relevant in the case where the medical treatment decision maker is providing consent for use of the patient’s information.

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/your relative, in hospital - may identify you/them.

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

Name of patient:
__________________________________________

I, __________________________________________ [name of patient, or Medical Treatment Decision Maker], consent for information about me / the patient 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, Medical Treatment Decision Maker:

______________________________

Date: ..... / ..... / ..... 

Requesting Author:

Print Name _________________________________________________

Date: ..... / ..... / ..... 

Signature ____________________________

Department/Unit ________________________