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| **SALHN Case Report Ethics Review Application Form** |
| This form is used to submit a case report to the SAC HREC for review. |

**Instructions**

A clinical case report is a report on an individual patient, that describes an unusual, rare, or novel event. They can also contribute to medical knowledge, provide opportunities for education and a positive change in clinical practice.

Traditionally, case reports have not been required to under full HREC review as they are negligible risk and retrospective in nature, however it is important they are do receive HREC review, to review to ensure the patient’s privacy and best interests have been considered.

Case reports should only conducted by clinicians/clinical care team and are not appropriate as a student project.

The SAC HREC strongly encourage case report authors to use and cite the CARE reporting guideline1 (or the appropriate discipline or context specific extension2) to encourage transparency and quality of the resulting output.

Normally, patient (or guardian) written, informed consent should be obtained to use their information and any images for this case report, using the provided consent form.

The lead author should be part of the patient’s clinical care team to access their medical records.

Your application will be reviewed by the SAC HREC or the appointed delegates, and you will be advised by return email if ethical approval has been granted and you are authorized to access the patients contact details to send the letter of introduction and consent form.

You are also required to provide a copy of the patient/guardian’s signed consent form and a copy of the publication/presentation to obtain the formal HREC approval letter.

**Submission guidelines**

Please provide:

* A completed and signed version of this Case Report Ethics Review Application Form.
* A copy of the Letter of Introduction and Consent Form

Please submit the application via email to Health:SALHNofficeforresearch@sa.gov.au.

Author/s details

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| Case report lead author name:Qualifications:Position: Organisation:Involvement in the case:Email address:Phone number:Please provide all of the above details for each additional co-author below.  |

Summary of case

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| Please provide a summary of the case, including de-identified patient information, why this case report is unique/significant and why this case report should be published/presented:Please provide a brief literature review, explaining what this case report adds to the literature. If you need support with completing this, please contact nikki.may@sa.gov.au who will be happy to assist you: |

Risk assessment

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| 1. Will you request a waiver of consent, is the patient unable to provide written, informed consent, or will third-party (e.g., guardian) consent be requested?

[ ]  Yes[ ]  No1. Will you include any images (still or video) in the case report?

[ ]  Yes[ ]  NoIf Yes, please provide a thorough description of any images to be used, including how the image(s) will be de-identified. If the case report uses potentially identifiable information, please explain why this required:1. Will the case report include any potentially identifiable or sensitive information?

[ ]  Yes[ ]  No1. Will the case report describe the care of a patient from a vulnerable population?

[ ]  Yes [ ]  NoIf Yes, please detail which population is involved and steps taken to ensure protection of the patient: |

Patient (or guardian) written, informed consent and perspective

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| Will you obtain the patient’s written, informed consent? [ ]  Yes [ ]  No If No, please advise why not:Will the patient be provided with an opportunity to review the manuscript and provide their perspective of the event?[ ]  Yes[ ]  NoIf no, please advise why not:What plan is in place, should the patient become distressed from re-living the event or you identify that further medical attention is required? |

Data management and dissemination plan

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| Where will the case report and any related images be stored?Who is responsible for the security of the data? Where will this case report be published, presented, or used? [ ]  Publication - please specify which one/s:[ ]  Conference / presentations - please specify the event: [ ]  Change of standard care[ ] Education |

Declarations

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| **Case report lead author:**I confirm the information provided in this form is true and correct.I confirm I will submit a copy of the publication / presentation to the SAC HREC when available.**Date**: Signature:  |

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| **Head of Department/Equivalent**I support this case report being produced and I confirm the information provided in this form is true and correct.**Name:** **Date**: Signature:  |

**Office use only**

**Research Governance Officer**

I confirm access to the patient’s medical records and personal information is appropriate for this case report, following HREC review.

**Name:**

**Date**:

Signature: 

**References**

1. Gagnier, J. J., Kienle, G., Altman, D. G., Moher, D., Sox, H., Riley, D., & CARE Group (2014). The CARE guidelines: consensus-based clinical case report guideline development. Journal of clinical epidemiology, 67(1), 46–51. https://doi.org/10.1016/j.jclinepi.2013.08.003

2. EQUATOR Network: https://www.equator-network.org/

For more information

# SALHN Office for Research Ward 6C / Room 6A – 219 Flinders Medical Centre Telephone: (08) 8204 6453

Email: Health.SALHNofficeforresearch@sa.gov.au [www.](http://www/) [SALHN Office for Research](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/about%2Bus/our%2Blocal%2Bhealth%2Bnetworks/southern%2Badelaide%2Blocal%2Bhealth%2Bnetwork/research)

Office for Research Case Report Form

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