# [SOP number] [SOP title]

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| Version | Vx.x |
| Author/s | [author name] |
| Approved | M Agar |
| Effective date | dd/mm/yyyy |
| Review date | dd/mm/yyyy |

**DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE**

**LATEST VERSION AS AVAILABLE FROM** [**www.uts.edu.au/itcc**](http://www.uts.edu.au/itcc)

**Introduction / Background**

Provide a context for the SOP and relate it to Good Clinical Practice (GCP). Provide a rationale why the SOP is needed.

**Objective**

State the objective of the SOP.

**Scope**

Scope refers to who the SOP might apply to or the extent of coverage of the SOP. What is included in the SOP and what might not be covered by the SOP.

**Ownership and Responsibility**

Specify the person(s) or role(s) that are responsible for implementing the SOP.

**Procedure**

Provide a clear and unambiguous description of the procedure that is to be followed.

**Related SOPs**

List all other SOPs related to this SOP

[SOP number] [SOP title]

**Related documents**

List all ITCC Templates and ITCC Guidance documents related to this SOP

[Template number] [Template name]

[Guidance doc number] [Guidance doc name]

List all other relevant documents related to this SOP

**References**

Example:

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 20/02/2020)

<https://www.ich.org/page/efficacy-guidelines>

Praxis Australia

List any/all other relevant references

**Acknowledgements**

List any/all acknowledgements

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| **History** | | | |
| Version | Date | Author | Reason |
| 1.0 | 25/05/2016 | D Currow | New procedure |
| 1.1 | 28/02/2018 | B Fazekas,  S Kochovska | Periodic review  Publication of the ICH GCP E6 (R2) |
| 1.2 | 20/02/2020 | J Lourdesamy | Periodic Review |
| [version] | dd/mm/yyyy | [author name] | [reason] |

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| **Approval** | | |
| Version | Approval Name | Approval Signature |
| 1.2 | [name of approver] |  |