STANDARD OPERATING PROCEDURE (SOP)

TITLE: RESEARCH RELATED COMPLAINTS

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Date:	Feb 26, 2020

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1. PURPOSE:

The purpose of this SOP is to outline the process for managing any complaints that may be received about research undertaken at, in association with or by Epworth.

Complaints may be made to Epworth about the conduct of research at Epworth or by Epworth affiliated researchers at external sites. Complaints may be made by research participants, researchers, staff or other interested persons or bodies.

2. SCOPE:

All research related complaints.

Where a complaint of allegation relates to research misconduct (i.e. a serious breach of the *Australian Code for the Responsible Conduct of Research 2018*[1] which is also intentional or reckless or negligent), SOP-RG-06 will apply instead (see Related Documents).

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in research related activities at or on behalf of Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

All persons involved in research, whether patients, research participants, staff or investigators, have a right to report or make complaints in relation to research-related matters directly or through a representative.

Persons wishing to lodge a study-specific complaint are encouraged to refer to the study Participant Information and Consent Form (PICF) and contact the study team directly in the first instance to discuss. Where this is not appropriate or the complaint is not study-specific, the complaint may be directed to the Epworth Research Development and Governance Unit (RDGU) in accordance with this SOP.

The complaint process will be confidential and managed in compliance with Chapter 5.6 (Handling Complaints) of the *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*[2], the *Health Services (Conciliation and Review) Act 1987* (Vic)[3] and, to the extent that the complaint concerns Epworth's handling of personal information or health information, with the *Privacy Act 1988* (Cth)[4] and the *Health Records Act 2001* (Vic)[5] and Epworth's Privacy Policy[6].

The resolution of a complaint from a research participant must be in accordance with any complaints procedure that is detailed in the study PICF. If there is such a complaints procedure, it

will take precedence over the procedures set out in this SOP. Complaints will be managed in a timely manner, whilst ensuring that complaints are properly investigated and procedural fairness is afforded to all interested parties.

Persons involved in research at Epworth may choose to make a complaint to an external body, such as the Australian Information Commissioner or the Health Services Commissioner (Victoria). Contact details for these external bodies are set out in Epworth's Privacy Policy published on the Epworth website[6].

5.1 All Complaints to Epworth

- Research-related complaints made to Epworth are to be directed to the Research Development and Governance Officer (RDGO) in the first instance (see Appendix A for contact details).
- Complaints regarding Epworth's handling of personal information or health information will be referred to Epworth's Privacy Officer.
- Informal Complaints (i.e. a verbal expression of dissatisfaction that can be dealt with promptly and to the complainant's satisfaction at the point of service) received by Epworth do not need to be recorded in the Complaints Register.
- Low-rated, study-specific complaints (see APPENDIX B for rating scale) managed by the study team do not need to be notified to the RDGO for recording in the Research Complaints Register unless the complaint is not able to or is not appropriate to be managed by the study team.
- Medium-rated complaints and high-rated complaints (see APPENDIX B) lodged in accordance with study-specific PICF complaints processes are to be notified by the study co-ordinator/PI to the RDGO for recording in the Research Complaints Register.
- Formal Complaints (i.e. all written, including email, incident reports or complaints and any verbal complaint that cannot be dealt with as an informal complaint) are to be recorded in the Research Complaints Register, maintained by the office of the (RDGU). The Register includes information to track the progress of a complaint and provide a history of all referrals and action taken, as well as the dates of receipt and resolution of the complaint. Hard copies of the details of the complaint, actions taken and outcomes will also be kept in the relevant project file, where appropriate. It is important to identify both the project number and the project title when registering a complaint or enquiry related to a specific project.
- Formal Complaints will be allocated a reference number (automatically allocated in RiskMan).
- External independent advice may be sought by Epworth to resolve the matter.

5.2 Complaints from research participants

- Study-specific complaints received from research participants in the first instance will be managed by the RDGO in conjunction with the relevant study co-ordinator and/or Principal Investigator.
- Complaints that cannot be readily resolved will be referred for consideration by the Group Director Research and Development (GDRD) and escalated as appropriate
- Where the research participant is an Epworth patient, the relevant Patient Liaison Officer will be notified of the complaint.

5. 3 Formal complaints from researchers

- Complaints from researchers about any aspect of the management of their research project by Epworth should be directed in the first instance to the RDGO.
- The RDGO will liaise with the complainant to resolve the matter in the first instance.
- Serious complaints that cannot be resolved using the processes above will be referred for consideration by the GDRD and escalated as appropriate.
- If the complaint involves the RDGO and the complainant does not feel comfortable raising it with the RDGO/GDRD they may choose to contact the Executive Director, Academic & Medical directly.

5.4 Post-complaint enquiries

Any enquiries made regarding the handling of incidents or complaints related to research should be initially directed to the RDGO, unless alternative contact details have previously been provided by Epworth.

6. REFERENCES AND RELATED DOCUMENTS:

1. Australian Code for the Responsible Conduct of Research 2018 https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

2. National Statement of the Ethical Conduct in Human Research 2007 (Updated 2018) https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

3. Health Services (Conciliation and Review) Act 1987 (Vic)

4. Privacy Act 1988 (Cth) https://www.legislation.gov.au/Series/C2004A03712

5. Health Records Act 2001 (Vic) https://www2.health.vic.gov.au/about/legislation/health-records-act

6. Epworth's Privacy Policy https://www.epworth.org.au/who-we-are/privacy-policy

7.1 Related Forms and Templates

N/A

7.2 Related SOPs

- SOP-RG-06 Research Misconduct
- SOP-Glossary-of-Terms

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A first issue

APPENDIX A EPWORTH COMPLAINTS CONTACT PERSON

Position	Research Development and Governance Officer
Telephone	(03) 9936 8058
Email	research@epworth.org.au

APPENDIX B Seriousness of Complaints

Complaints will be rated on a scale for seriousness when they are first received and again when they are closed in order to help with more accurate assessment of seriousness. A single complaint can often raise several issues of varying seriousness.

a. Low-rated complaints - those that are easily resolved by telephone or a letter with an explanation. These may include misunderstandings or misconceptions where a detailed investigation is unwarranted.

b. Medium-rated complaints - those involving incidents such as misunderstandings, access to records, disputes about costs, discourtesy, protocol violations, breaches of privacy without serious consequences and diagnostic or treatment errors without serious consequences.

c. High-rated complaints - those involving significant quality assurance implications, practices that need changing to avoid recurrence of an event, such as amendments to the study protocol, or development of a new policy or procedures. In addition, they include complaints about serious breaches of GCP, breaches of privacy, personal injury, professional misconduct, fraud, unlawful or unethical acts, lack of informed consent and diagnostic or treatment errors with serious adverse events.