

STANDARD OPERATING PROCEDURE (SOP):

TITLE: MONITORING OF TEMPERATURE CONTROLLED AREAS



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1. PURPOSE:

The purpose of this SOP is to document the procedure for temperature monitoring of storage areas for Investigational Medicinal Products (IMP), other temperature sensitive products (e.g. ancillary supplies such as laboratory kits) and biological samples.

2. SCOPE:

The principles of this SOP may be applied to any temperature controlled storage area for materials used in a clinical trial.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons who store temperature sensitive materials in facilities during a clinical trial at Epworth.

4. GLOSSARY OF TERMS:

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

5. PROCEDURE:

5.1 Monitoring of Temperature Controlled Areas

- All fridges and freezers that Epworth uses to store clinical trial laboratory samples must be continually temperature monitored. Readouts of the temperature monitoring should be made available, whenever requested. Monthly readouts should be stored in SiteDocs by the relevant Clinical Trial Coordinator or Research Nurse.
- If Epworth clinical research staff are responsible for the storage of the Investigational Product (IP), the IP must be stored in a locked, restricted access location which is temperature monitored. Generally IP is managed and stored at the Slade Pharmacy who maintain temperature monitoring and records for the IP.

6. REFERENCES:

N/A

7. RELATED DOCUMENTS:

N/A

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8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A First Issue

9. APPENDIX

N/A