STANDARD OPERATING PROCEDURE (SOP)

TITLE: HANDLING AND SHIPPING OF BIOLOGICAL SAMPLES

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1. PURPOSE:

The purpose of this SOP is to document the procedures for handling and shipping of clinical research biological samples (including but not limited to excreta, secreta, blood and its components, tissue and tissue fluids) at Epworth Healthcare.

Correct handling and shipping procedures are vital in ensuring the integrity of samples and the safety of all individuals involved in the sample management and shipping processes.

2. SCOPE:

All Clinical Research conducted at Epworth

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons involved in the handling and shipping of biological samples in clinical research at Epworth.

4. GLOSSARY OF TERMS:

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

5. PROCEDURE:

The Principal Investigator (PI) is responsible for ensuring study team members are appropriately trained and delegated to handle and ship biological samples in accordance with this SOP. The PI can delegate at his/her discretion certain duties to suitably qualified individuals. Delegation of activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 Certification for Handling and Shipping of Biological Substances, category B and/or Dangerous Goods

Line managers should:

- Ensure all research staff who handle or ship biological samples (Biological Substances, Category B) or Dangerous Goods have undertaken, passed and hold a current International Air Transport Association (IATA) approved, Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packing and Shipping certificate.

All Epworth clinical research staff should:

- Be aware that re-certification is required every two years, and that certificates must be kept for a minimum of 3 years from the most recent training completion date and must be available upon request to CASA.

5.2 Handling and Storing - Biological Sample Management

The person handling specimens should:

- Obtain all the sample management details from the Sponsor or central laboratory if not already described in the protocol, including:
    1. Central laboratory contact information
    2. Requirements for specimen collection, labelling, processing and storage
    3. Packing and shipping specifications
- The Sponsor, or whoever is listed in the Research Agreement should provide all supplies (such as kits, lab equipment and bulk supplies) and instructions for sample management prior to study activation. For investigator initiated studies, it is the responsibility of the PI to ensure the study is adequately resourced prior to commencing.
- Process and transfer samples to an appropriate storage container as per protocol instructions.
- Dispose of any unused or waste specimens in accordance with the relevant Epworth Waste Management Protocol[1-8] (see Section 6 References).
- Store the samples in a secure location under the required storage conditions outlined in the trial protocol. Restricted access to samples should be in place as well as clearly marked samples/shelves.
- Ensure all laboratory equipment used for the clinical research– such as refrigerators/freezers, centrifuges and thermometers are serviced and maintained routinely and temperature logs maintained. Maintenance documentation should be available and updated as the equipment is serviced. Refer to SOP-TM-10: Maintenance of Equipment and SOP-TM-11: Maintenance of Temperature Controlled Storage Areas.
- Ensure that in the case of storage equipment failure, that suitable back-up storage is available to maintain integrity of samples.

5.3 Shipping of Biological Samples

The person shipping specimens must:

- Have the appropriate IATA certification to handle and ship samples by air.
- Ensure that samples are handled and packed in accordance with Sponsor requirements and relevant IATA classifications.

- Follow the Sponsors instructions to determine/confirm the proper timing for samples shipments to ensure that the receiving laboratory will be open on anticipated day of delivery to prevent specimen spoilage.
- Review packaging requirements and package the sample(s) as specified in the protocol and/or lab manual.
- Complete the required documentation.
- Retain a copy of the shipping receipt/courier waybill and commercial invoice to keep in the Investigator Site File (ISF) (see SOP-TM-02: Investigator Site File and Essential Documentation) and send to the Sponsor, if required.

5.4 Tracking of Handling and Shipping of Biological Samples

The person shipping specimens should:

- Ensure that documentation related to the shipping of Category B specimens and/or Dangerous Goods is kept and filed in the ISF to facilitate the tracking of shipments and satisfy GCP requirements (see SOP-TM-02: Investigator Site File and Essential Documentation)

6. REFERENCES:

1. Brighton Waste Management Protocol
2. Camberwell Waste Management Protocol
3. Cliveden Waste Management Protocol
4. Epworth Eastern Waste Management Protocol
5. Freemasons Waste Management Protocol
6. Geelong Waste Management Protocol
7. Hawthorn Waste Management Protocol
8. Richmond Waste Management Protocol

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

N/A

7.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-TM-02 Investigator Site File and Essential Documentation
- SOP-TM-10 Maintenance of Equipment
- SOP-TM-11 Temperature Controlled Storage Areas

8. VERSION CONTROL

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

9. APPENDIX

N/A