Document Type:	SOP	**Document Date:**	9th January 2007
Study Name:	HUSERMET	**Version Number:**	2.0

Title	**Receipt, Dispatch and Disposal of Serum Samples**
Author/s	
Version Number	2.0
Active Date	28th March 2007
Previous Version Number	1.0
Changes From Previous Version	Inclusion of annotated spreadsheet and checking of samples upon receipt.
Related Documents	Study Protocol Analytical Operations Manual SOP HU007 - Sample Tracking Sample Dispatch Contact List
Abstract	This Standard Operating Procedure (SOP) is for use, in the LINK funded, "Human Serum Metabolome in Health and Disease Study" (HUSERMET), by group at the University of Manchester for the quality control of consumables utilised in the HUSERMET project for the metabolomic analysis of human serum samples.

TABLE OF CONTENTS

1. INTRODUCTION 3

2. HEALTH AND SAFETY 3

3. PROCEDURES 4

3.1. SAMPLE RECEIPT 4
3.2. SAMPLE DISPATCH 5

3.3. SAMPLE DISPOSAL 5

4. ABBREVIATIONS 6

5. APPENDIX 7

5.1. APPENDIX 1: SAMPLE TRANSFER/RECEIPT FORM 7
5.2. APPENDIX 2: CRYOBOX EXCEL SPREADSHEET FOR RECEIVED SAMPLES 8
5.3. APPENDIX 3: ANNOTATED CRYOBOX EXCEL SPREADSHEET FOR RECEIVED SAMPLES 9
5.4. APPENDIX 3: CRYOBOX EXCEL SPREADSHEET FOR DISPATCHED SAMPLES 10
5.5. APPENDIX 4: SAMPLE DISPOSAL FORM 11

1. INTRODUCTION

This document details the procedures to be followed, during the conduct of the LINK funded, "Human Serum Metabolome in Health and Disease Study" (HUSERMET), for the receipt of serum samples at the School of Chemistry; the dispatch of serum samples to AZ, GSK and Stepping Hill Hospital from the School of Chemistry; and the disposal of serum samples at the School of Chemistry.

2. HEALTH AND SAFETY

2.1. Work is only to be performed by trained and competent staff. The senior post-doctoral research associate is responsible for staff training and ensuring compliance with all local health and safety requirements. A complete list of staff that are authorised to conduct the procedures described in this SOP is maintained by the senior post-doctoral research associate.

2.2. Appropriate Personal Protective Equipment (PPE), such as gloves, should be used in the laboratory as necessary. Laboratory coats and safety spectacles must be worn in the laboratory at all times. The handling of all biological material, chemicals, acids, solvents and reagents should be in strict accordance with the manufacturer's safety data sheet, the Control of Substances Hazardous to Health (COSHH) assessment and local laboratory policy.

2.3. When handling dry ice and samples from the -80ºC freezer there is risk of cold burn and frost bite. Appropriate cold resistant gloves must be worn when handling samples and containers maintained at -80ºC or those on dry ice.

3. PROCEDURES

3.1. Sample Receipt

3.1.1. Serum samples will be received by the University of Manchester in barcode labelled cryovials (Greiner, part numbers 122261/122263) stored in barcode labelled 10x 10 Cryoboxes (Greiner, part number TR100N).

3.1.2. Upon receipt of samples the Sample Transfer/Receipt Form (Appendix 1), which will be included with the samples, will be checked against samples and, if provided, the Excel spreadsheet (an example is shown in Appendix 2).

3.1.3. The samples should be checked for the following:

1. Packaging is complete and undamaged.
2. Box numbers match those detailed on the Sample Transfer/Receipt Form and the Cryobox Excel spreadsheet.
3. Aliquot numbers match those detailed on the Sample Transfer/Receipt Form.
4. Evidence of thawing in transit or during packing.
5. Evidence of haemolysis (pinking of the samples).
6. Volume, ensure that volumes are, by eye, what has been detailed in the operation manual.

3.1.4. Any discrepancies should be noted on the Sample Transfer/Receipt Form, use an additional page if more information required. Immediately report any discrepancies to the Project Manager.

3.1.5. The completed Sample Transfer/Receipt Forms will be held by the Project Manager. Once checked the samples will be logged into the sample tracking database (SOP HU007 - Sample Tracking) and placed in a -80ºC freezer.

3.1.6. A copy of the completed Sample Transfer/Receipt Forms will be faxed and/or posted to the contributing site, or a nominated agent, by the Project Manager.

3.1.7. The Excel spreadsheet (Appendix 2) should be annotated to indicate that the volumes ststed in the operations manual are present (check by eye) and for the presence of haemolysis. Add three columns to the Excel spreadsheet Volume, Haemolysis and Comments (Appendix 3)

3.1.8. Add comments as indicated below:

- Volume: OK/Low/Comment
- Haemolysis: Yes/No

- Comments: free text field

3.1.9. To indicate that the box map has been annotated the investigator should initial and date the Excel spreadsheet as shown in Appendix 2.

3.1.10. Save the Excel spreadsheet as "*original name*_annotated". A copy should be saved to the Server and a copy e-mailed to the Project Manager.

3.2. Sample Dispatch

3.2.1. Samples may be dispatched from the University of Manchester for analysis at three sites:

- GSK.
- AZ.
- Stepping Hill Hospital.

An up to date list of delivery contact details will be maintained by the Project Manager and be made freely availbale to reserachers via a study folder available from the Server.

3.2.2. Cryovials for dispatch should be placed into a 10x10 Cryobox. As each cryovial is placed into the Cryobox its barcode should be scanned into a Cryobox Excel spreadsheet (Appendix 4). The box should be given a unique alphanumerical identifier consisting of three digits prefixed with the letter U. The label should be placed on the bottom, left hand corner of the front face of the Cryobox.

3.2.3. The Cryobox should be stored at -80ºC until it is to be shipped. The Cryobox/es should be p[laced in a biohazard envelope and shipped on dry ice for next/same day delivery. The Cryobox/es should be dispatched along with a Sample Transfer/Receipt Form and a print out of the Cryobox Excel spreadsheet for the box/es.

3.2.4. Prior to shipment the receiving site should be informed by the Project Manager and agreement received that samples can be dispatched.

3.2.5. The Project Manager will maintain an up to date list of contact details for sample dispatch. This will be freely available to all working on the HUSERMET project.

3.3. Sample Disposal

3.3.1. In the event of a subject withdrawing from the study any samples held by the University of Manchester will be destroyed. A Sample Disposal Form (Appendix 4) requesting disposal will be received by the Project Manager.

3.3.2. This form will be completed by the laboratory staff member who disposes of the samples. The samples should be placed in a clinical waste bag and sent for disposal with all other clinical waste.

3.3.3. The completed Sample Disposal Form will be held by the Project Manager.

4. ABBREVIATIONS

AZ	AstraZeneca
COSSH	Control of Substances Hazardous to Health
GSK	GlaxoSmithKline
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure

5. APPENDIX

5.1. Appendix 1: Sample Transfer/Receipt Form

Sample Transfer/Receipt Form: HUSERMET Study

Packed by:			
Address:			
Packing Date:		**Shipping Date:**	
Storage Conditions:			
Contents:			
Notes:			
Signature:			
Print Name:			
Date:		**Time:**	
Received by:			
Address:			
Date Of Receipt:		**Time of Receipt:**	
Notes:			
Signature:			
Date:		**Time:**	

5.2. Appendix 2: Cryobox Excel Spreadsheet for Received Samples

An example of the Excel spreadsheet for the first 30 positions of Box No. B0210.

Box No:	B0210			
Position_y	**Position_x**	**Aliquot No.**	**Blood Collection Tube No.**	**Sample**
A	**1**	0201010001	02010001	Serum
A	**2**	0201020001	02010001	Serum
A	**3**	0201030001	02010001	Serum
A	**4**	0201040001	02010001	Serum
A	**5**	0201050001	02010001	Serum
A	**6**	0201060001	02010001	Serum
A	**7**	0201070001	02010001	Serum
A	**8**	0201080001	02010001	Serum
A	**9**	0201090001	02010001	Serum
A	**10**	0201100001	02010001	Serum
B	**1**	0201010002	02010002	Serum
B	**2**	0201020002	02010002	Serum
B	**3**	0201030002	02010002	Serum
B	**4**	0201040002	02010002	Serum
B	**5**	0201050002	02010002	Serum
B	**6**	0201060002	02010002	Serum
B	**7**	0201070002		Empty
B	**8**	0201080002		Empty
B	**9**	0201090002		Empty
B	**10**	0201100002		Empty
C	**1**	0201010003	02010003	Serum
C	**2**	0201020003	02010003	Serum
C	**3**	0201030003	02010003	Serum
C	**4**	0201040003	02010003	Serum
C	**5**	0201050003	02010003	Serum
C	**6**	0201060003	02010003	Serum
C	**7**	0201070003	02010003	Serum
C	**8**	0201080003	02010003	Serum
C	**9**	0201090003	02010003	Serum
C	**10**	0201100003		Empty

5.3. Appendix 3: Annotated Cryobox Excel Spreadsheet for Received Samples

An example of the annotated Excel spreadsheet for the first 30 positions of Box No. B0210.

Box No:	B0210	**Annotated by**	AH	**Date**	01/04/07		
Position_y	**Position_x**	**Aliquot No.**	**Blood Collection Tube No.**	**Sample**	**Volume**	**Haemolysis**	**Comment**
A	**1**	0201010001	02010001	Serum	OK	No	
A	**2**	0201020001	02010001	Serum	OK	No	
A	**3**	0201030001	02010001	Serum	OK	No	
A	**4**	0201040001	02010001	Serum	OK	No	
A	**5**	0201050001	02010001	Serum	OK	No	
A	**6**	0201060001	02010001	Serum	OK	No	
A	**7**	0201070001	02010001	Serum	OK	No	
A	**8**	0201080001	02010001	Serum	OK	No	
A	**9**	0201090001	02010001	Serum	OK	No	
A	**10**	0201100001	02010001	Serum	OK	Yes	
B	**1**	0201010002	02010002	Serum	OK	No	
B	**2**	0201020002	02010002	Serum	OK	No	
B	**3**	0201030002	02010002	Serum	OK	No	
B	**4**	0201040002	02010002	Serum	OK	No	
B	**5**	0201050002	02010002	Serum	OK	No	
B	**6**	0201060002	02010002	Serum	OK	No	
B	**7**	0201070002		Empty	Comment	No	Not empty
B	**8**	0201080002		Empty	OK		
B	**9**	0201090002		Empty	OK		
B	**10**	0201100002		Empty	OK		
C	**1**	0201010003	02010003	Serum	OK	No	
C	**2**	0201020003	02010003	Serum	Low	No	
C	**3**	0201030003	02010003	Serum	OK	No	
C	**4**	0201040003	02010003	Serum	OK	No	
C	**5**	0201050003	02010003	Serum	OK	No	
C	**6**	0201060003	02010003	Serum	OK	No	
C	**7**	0201070003	02010003	Serum	OK	No	
C	**8**	0201080003	02010003	Serum	OK	No	
C	**9**	0201090003	02010003	Serum	OK	No	
C	**10**	0201100003		Empty	OK	No	

5.4. Appendix 3: Cryobox Excel Spreadsheet for Dispatched Samples

An example of the Excel spreadsheet for the first 30 positions of Box No. U0001

Box No:	U0001	
Position_y	**Position_x**	**Aliquot No.**
A	**1**	0101010001
A	**2**	0101020001
A	**3**	0101010002
A	**4**	0101020002
A	**5**	0101010003
A	**6**	0101020003
A	**7**	0101010004
A	**8**	0101020004
A	**9**	0101010005
A	**10**	0101020005
B	**1**	0101010007
B	**2**	0101020007
B	**3**	0101010008
B	**4**	0101020008
B	**5**	0101010009
B	**6**	0101020009
B	**7**	0101010012
B	**8**	0101020012
B	**9**	0101010013
B	**10**	0101020013
C	**1**	0101010014
C	**2**	0101020014
C	**3**	0101010015
C	**4**	0101010015
C	**5**	0101020022
C	**6**	0101010022
C	**7**	0101020023
C	**8**	0101010023
C	**9**	0101020025
C	**10**	0101010025

5.5. Appendix 4: Sample Disposal Form

Sample Disposal Form: HUSERMET Study

Requested By:			
Address:			
Site No:		**Subject No:**	
Requested To:			
Storage Address:			
Reason for Disposal Request:			
Signature:			
Print Name:			
Date:		**Time:**	

Disposed by:			
Address:			
Date Of Disposal:		**Time of Disposal:**	
Method:			
Signature:			
Date:		**Time:**	

SIGNATURE PAGE

I agree:

- That I have read and understood SOP HU001.