LIFE STUDY | Understanding lives – now and for the future

Standard Operating Procedures: Biosamples

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Contents

1 Background

Initial discussions regarding child development assessments took place in 2009 as part of the original grant submission for Life Study. Following confirmation of funding in 2011, the Life Study Scientific Protocol Development Group and Scientific Working Group on Biological Samples were established and met to develop on the original measures proposed in the protocol. Consideration was given to potential research questions that could be answered by Life Study, and also the exciting opportunities for novel approaches to be included, taking into account the biological samples collected in other cohort studies and the overarching objectives of Life Study. A consultative meeting and a web-based consultation on the protocol were held in 2012.

NatCen Social Research conducted a pilot of the pregnancy component clinic based procedures including biosample collection and their staff were involved in the initial development of the Biosample SOPs. Biosamples to be collected from mothers and babies at birth were piloted at University College Hospital London as part of the Wellcome Trust Infection and Immunity enhancement pilot. The SOPs for collecting placentas were developed and piloted by Professor Sebire and colleagues at the National Institute of Health Research Biomedical Centre at Great Ormond Street Hospital for Children NHS Foundation Trust.

The Life Study SOPs for Biosamples were further refined and extended in partnership with UK Biocentre which was appointed as the Life Study biorepository services partner in 2015 following a formal procurement exercise carried out by University College London.

Members of the Life Study team based at UCL Institute of Child Health gave feedback on draft documents, sourced equipment, tested data capture mechanisms and liaised with external suppliers regarding the specification and development of data capture systems.

Staff in the first Life Study Centre based in the Barking Havering and Redbridge University Hospitals NHS Trust, gave feedback on their experiences in collecting samples from participants. This feedback was incorporated in subsequent versions of the SOPs.

The Life Study Scientific Steering Committee was responsible for overall decision making and for approval of the final Life Study scientific protocol. This included making decisions as to which assessments, measurements and observations were included for participants attending the Life Study Centres.

The SOPs presented in this document are those which were in use for the core Life Study protocol when funding for Life Study was withdrawn in October 2015. The Wellcome Trust funded Infection and Immunity Baby Biome Study continues (see www.ucl.ac.uk/babybiome-study for more information).

2 SOP: Collection of Blood and Urine Samples

2.1 Purpose

The purpose of this SOP is to describe the correct procedure to collect blood and urine samples from participants attending the pregnancy and the twelve month visits at the Life Study centre and to enable Life Study centre staff to perform phlebotomy and handle blood and urine samples safely and to the required standards of quality.

2.2 Responsibilities

Staff who have successfully completed the NHS Trust phlebotomy training will be responsible for collecting blood samples and for assisting participants to provide the urine sample. The Centre Manager will ensure that all Life Study Centre staff are trained in and comply with this SOP.

2.3 Definitions

Terminology	Definition
SOP	Standard Operating Procedure
SST	Serum Separator Tube
PST	Plasma Separator Tube
EDTA	Ethylenediaminetetraacetic acid
RNA	Ribonucleic acid
Set of vacutainers	The group of vacutainers tubes to collect four blood samples from one participant (green, orange, purple, blue tops) and a pot to collect one urine sample

2.4 Training

Training in phlebotomy will be provided by the NHS Trust hosting the Life Study Centre. Staff without a clinical qualification will be required to undertake the Life Study phlebotomy training and assessment prior to performing venepuncture unsupervised.

2.5 Equipment

- Urine collection kit (biohazard ziplock bag containing one urine pot and one vacutainer with brown top)
- 4 vacutainers tubes (green, purple, orange and blue top)
- Label stickers
- Phlebotomy tray/ kidney dish
- Tourniquet
- 21g/23g needles or butterfly needles with connector

- Tube holder
- Cotton balls
- Skin disinfectant
- Sharp bin
- Plaster or micropore tape

2.6 Related Documents

- NHS Trust policy for needle stick injury
- NHS Trust policy for management spillages of biological substances
- Life Study Phlebotomy Training and Assessment form
- Life Study SOP Processing of Blood and Urine Samples

2.7 Health and Safety

Gloves must always be worn when handling blood samples, and if desired and as an additional precaution, two pairs of gloves may be worn.

Staff handling samples must have completed the NHS Trust training on health and safety and read the relevant policies.

2.8 Pre-requisite: Participant Consent

Participant consent to take part and provide a biological sample must be obtained and appropriately recorded before collecting any biosamples. Participants may decline or withdraw their consent to at any point during the appointment and continue to be part of the study.

If consent is withdrawn after samples have been collected follow the procedure set out in the SOP 'BIO 037 Participant Withdrawal' (see Section 11).

2.9 Collection of Urine Samples

After consent has been obtained mothers and their partners will be:

1 Provided with one urine collection pack (consisting of one urine pot and one pre-barcoded Vacutainer tube (Brown cap) in a plastic biohazard bag)

2 Invited to give a sample of urine following the instructions on the urine collection poster displayed in the toilet.

NOTE: warn the participant NOT to peel the label off the blue lid as it covers a needle

3 Asked to hand the sample in the biohazard bag to their assigned Life Study Midwife or Research Assistant

2.10 Collection of Blood Samples

a) Equipment Preparation

1 Place four vacutainers tubes (one of each colour), two needles, one tube holder, cotton balls, skin disinfectant and micropore tape or a plaster in the clinical tray

2 Check that all vacutainer tubes have a barcode label and are within their expiry date

3 Check that all equipment is intact and within the expiry date

4 Prepare two sticker labels, one for the blood samples and one for the urine sample

b) Venepuncture

1 Invite the participant to be seated on the phlebotomy chair and explain that you would like to collect four blood samples (about two to three tablespoons)

2 Ask the participant whether they have ever had any previous problems giving a blood sample and, if so, what was the difficulty. If the participant reports previous difficulties then consider using butterfly needle in veins on back of hand. If you have any doubts about proceeding then discuss this with the Life Study Centre Manager or midwife on duty before continuing

3 If the participant reports no previous problems, ask them to remove any clothing from their forearm to allow assessment and selection of a suitable vein.

4 Look for a suitable vein in front of the elbow: surface veins in the inner elbow (e.g. cephalic, or cubital veins: see Figure 1) are usually best for venepuncture.

5 Ask the participant if they have a preferred site for the procedure based on their experience.

6 Wash your hands in the dedicated sink before collecting blood and put on a pair of gloves.

NOTE: for each participant use a new pair of disposable gloves. Blood must be taken using aseptic technique and should be considered potentially infectious and handled accordingly as per NHS Trust policies

7 Ensure the participant is sitting comfortably with their arm in a downwards position supported on the arm rest

8 Gently palpate the selected vein to assess suitability and select site for venepuncture.

TIPS

A good vein for venepuncture should feel bouncy and soft, be straight and refill when compressed. Avoid veins that are bruised, thin, hard or near a bony prominence.

If the veins are not very visible, tap the skin with your finger lightly over the place you expect to find them and instruct the participant to clench and unclench their fist, or allow the arm to hang down at the participant's side.

If veins on this arm appear unsatisfactory, consider the other arm (with a tourniquet in place).

Failing this, consider using a vein lower down the arm.

If a suitable vein cannot be found in the forearm ask permission to collect sample from veins one the back of the hand using a butterfly needle.

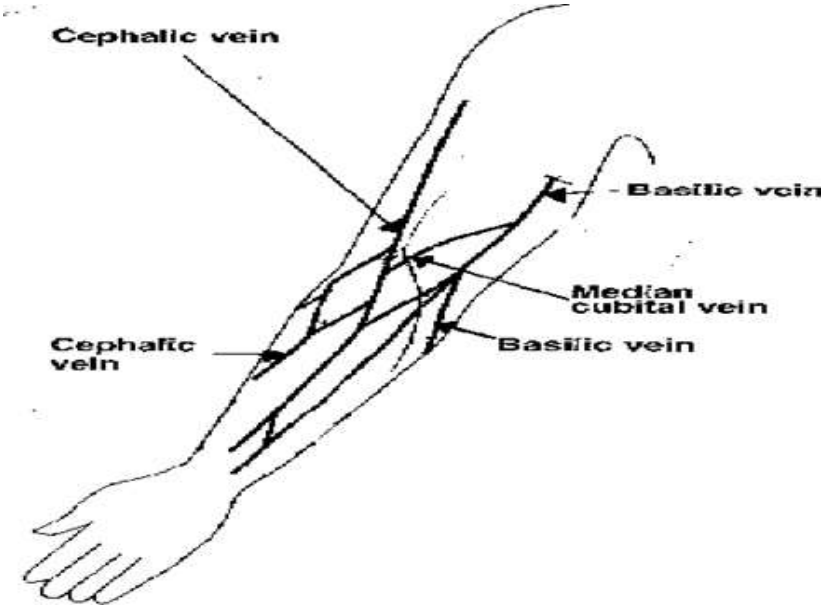


Figure 1 Diagram showing principal veins of the forearm

9 Once the final site has been selected, apply a tourniquet to the upper arm on the chosen side (approximately 7–10 cm above the intended venepuncture site). It should be moderately tight and should NOT be in place for longer than one and a half minutes.

10 Clean the area with skin disinfectant and allow at least 30 seconds to dry

NOTE: The skin must be dry before inserting the needle as alcohol may cause pain and also may result in haemolysis of the blood collected

11 Screw the needle into the needle holder and remove the cap

12 Use one hand to draw the skin towards participant's hand so that it is tight over vein. Hold the tube holder between the thumb and index finger, with the needle along the line of the vein at approximately a 15-30 degree angle to skin. Ensure the bevel of the needle is in an upwards position and insert the needle through the skin into the vein

13 Hold the tube holder steady with one hand and select, with the other hand, the first vacutainer tube in the sequence shown in Table 1 below. Push the tube into the holder until the sharp end of the needle within the barrel pierces the rubber bung of the tube.

14 Release the tourniquet as blood begins to flow into the vacutainer tube, but keep some pressure/tightness on the tourniquet if the blood flow appears slow

Order of collection	Cap Colour	Vacutainer tube (preservative)
1	Purple	EDTA
2	Green	Li Hep – PST
3	Orange	Clot activator – SST
4	Blue	RNA

Table 1 Order of Collection of Blood Samples

15 When the first vacutainer is full, the blood flow will cease. Remove the tube from the barrel and insert the second vacutainer. Gently invert the first vacutainer tube about ten times while the second vacutainer is filling. Repeat this step for all four tubes.

NOTE: If you are unable to invert the tube while the next vacutainer is filling invert all tubes immediately upon completion of blood sampling. The last vacutainer - Blue RNA - must be shaken vigorously for 20 seconds immediately after the sample is obtained.

Tip: If blood flow slows during collection, re-apply tourniquet and ask participant to clench and unclench their fist while keeping their arm still. When blood starts to flow, release the tourniquet and continue collection. If blood flow does not re-start, explain the problem to the participant and ask their permission to repeat venepuncture in the other forearm or to collect a sample from the veins in the back of the hand using a butterfly needle

16 After blood collection is complete (with either all required vacutainers filled or as many as possible), apply a clean cotton wool dressing over the skin at the

point of insertion of the needle. Remove the needle and apply pressure on the cotton wool at the venepuncture site

17 Ask the participant to maintain pressure on the cotton wool long enough to stop bleeding and elevate the arm slightly in order to help minimise risk of bruising.

NOTE: advise the participant not to bend their arm as this may result in a haematoma

18 Dispose of the vacutainer holder and needle as a single unit into the sharps bin immediately upon removal from vein. **Do not attempt to re-sheath the needle**

19 Ask the participant whether they have any allergy to plasters/tape. If so, use a hypoallergenic dressing.

20 Once bleeding has ceased, remove the cotton wool dressing from the participant's arm and apply a plaster or hypoallergenic dressing to cover the puncture site. If bleeding persists, reapply pressure with the cotton wool dressing and repeat this process a few minutes later

21 Once the plaster has been applied, than the participant for their sample and, if a urine sample hasn't been provided as yet, remind them that this is still required

2.11 Preparation for Processing

1 After all vacutainer tubes have been inverted around ten times (as per step 15 above), place them inside the biohazard bag and place the bag into the sample holder cup so that the tubes stay upright

2 Complete the two label stickers with participant details (Figure 2).
NOTE Record time of collection from the computer clock. Time must be accurate to allow lab staff to calculate the clotting time for the SST Orange tube. For the urine sample ask the participant for an approximate time when the sample was obtained and write 'URINE' on the label.

Participants' ID
Name
DOB
Time of collection: Collected by:
Reason sample not taken
Refused ☐ Failed ☐

Figure 2 Label to be completed with participant details

NOTE: if a sample is not collected select the reason on the sticker label and apply this to the empty vacutainer tube or urine pot. The empty tube/pot must be taken to the processing room following the same procedure as for filled tubes/pot so that lab staff can enter the relevant information on the biosamples administrative data system.

3 Apply the stickers on the blood and urine biohazard bags and put the blood vacutainer tubes s back into the samples holder cup in an upright position.

4 Take all samples to the processing room without delay

IMPORTANT: The last samples of the day must be obtained no later than 45 minutes before the pick-up to allow sufficient to process and prepare samples for shipment.

3 SOP: Processing Blood and Urine Samples

3.1 Purpose

The purpose of this document is to describe the procedures for processing blood and urine samples collected from participants in the Life Study Centre and to enable Life Study Centre staff to process biological samples safely and to required quality standards

3.2 Responsibilities

It is the responsibility of the Biosamples Leads and the Centre Manager to oversee and ensure the procedures are carried out in accordance with this document and in a safe and accurate manner.

It is the responsibility of the staff working in the processing room to carry out this procedure in accordance with this SOP.

3.3 Definitions

Terminology	Definition
SOP	Standard Operating Procedure
SST	Serum Separator Tube
PST	Plasma Separator Tube
EDTA	Ethylenediaminetetraacetic acid
RNA	Ribonucleic acid
Set of vacutainers	The group of vacutainers tubes to collect four blood samples from one participant (green, orange, purple, blue tops) and one urine sample

3.4 Training

Training is provided to the Biosamples Leads in first instance. The Biosamples Leads are responsible for training all other member of staff. Training will be also achieved by reading this SOP and undertaking practical work in the processing room. On completion of training, staff will complete and sign the Life Study samples processing training form.

3.5 Related Documents

- SOP Collection of Blood and Urine Samples
- SOP Preparing Samples for Transportation BIO037_02 v1.0
- SOP Life Study Courier Collection BIO037_03 v1.0
- Creating a Pregnancy Sample Manifest using version 5.7 (appendix A)
- Survey Management System training manual
- NHS Trust sharps and clinical waste disposal policy

3.6 Health and Safety

Wear gloves when handling blood and urine samples, and as an additional precaution two pairs of gloves can be worn. In the event of needle stick injury report to the Centre manager and follow the NHS Trust procedure.

3.7 Equipment

- Vacutainers rack
- Stop- watch
- Barcode scanner connected to the PC/ laptop
- Non-refrigerated centrifuge
- Dummy sample tubes for counterbalancing the centrifuge cycle

a) Using the Centrifuge

1 There are two centrifuges each of which has four buckets, which can hold up to four sample tubes each (Figure 3)

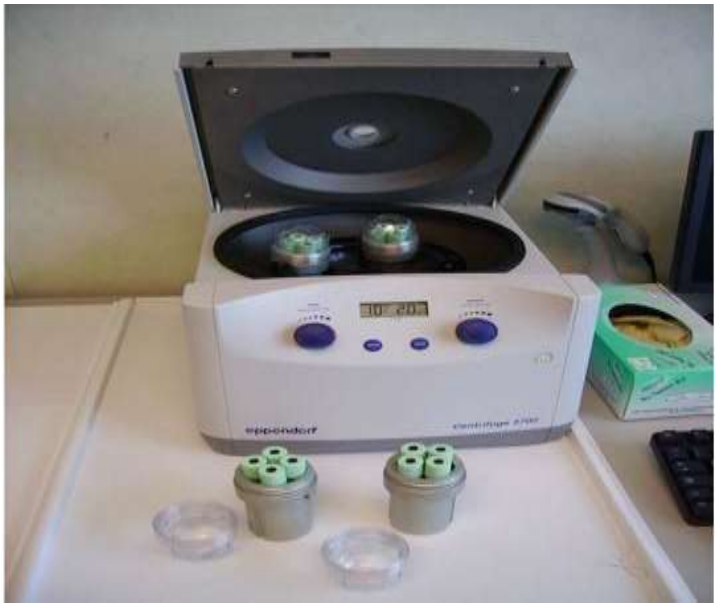


Figure 3 Centrifuge

2 Balance each bucket with its opposite partner in terms of its contents, either containing none or 4 tubes. The tube contents of each bucket must be balanced & counter balanced. For example: Full tubes are counter balanced with full tubes and empty tubes are counter balanced with empty tubes

3 Correctly attach the lids to the buckets before starting the centrifuge. Figure 4 2 shows a centrifuge containing PST tubes in all 16 positions with the lids in place ready for centrifugation.

Figure 4 Centrifuge ready for centrifugation

4 Check that the centrifuge has been set with brakes on. With the lid open press the “short” button which will show the current status of the brakes. If this needs changing, keep the short button depressed until “brake on” is displayed

3.8 Sample Processing

Sample processing comprises those laboratory and data entry procedures required to prepare blood and urine samples for further processing and long term storage at UK Biocentre.

At the start of the day log on to the Survey Management System and open up a new shipping manifest spreadsheet. Samples must be processed immediately after collection by following the steps below:

1 Place each set of samples from one participant in the tube rack and allocate one timer per set of samples

2 Check that the participant's details on the blood and urine sticker labels match

3 Set the stop watch to 30 minutes to measure the clotting time for the SST sample (orange top)

4 Transfer the urine into the brown vacutainer tube and place the tube in the rack next to the blood tubes. Dispose of any leftover urine in the toilet and discard the plastic cup in the clinical waste bin and the lid in the sharp box, as it contains a small needle

5 Find the participant on Life Study Survey Management System. Click on the participant's name and then click on the downwards arrow on the top bar. Select the Biosamples tab

6 Open the shipping manifest, click 'Add New Sample Manifest' and enter the data prompted by the template:

- Date
- Participant ID
  - *Is the Participant ID same as the Family ID?*
    YES: if the participant is the mother.
    NO: if the participant is the partner. Enter the Family ID if the participant is the partner
- Sample identification number (barcode)
  - *Scan the tube barcode*
    NOTE: after scanning the barcode move the tube back by one place in the rack to mark that the sample was recorded on the shipping manifest
- Date/ time sample collected from participant
- Date/ Time centrifuged.
  - *This is only required for the PST tube (green top)*

NOTE: see Appendix A for creating the pregnancy manifest

7 Return to the Survey Management System and select the PST sample from the list of biosamples. Complete the following fields:

- 'Sample GUI'. *Delete the existing code and scan in the sample barcode*
- Sample taken
- Time sample was taken

NOTE: Remember to save the data, the 'save' icon is at the bottom right of the page

8 Place the PST tube (green top) in the centrifuge and counterbalance as necessary using the dummy tubes.

9 Press START to activate the centrifuge. The cycle will last 10 min

10 Complete the Survey Management System fields in step 7 for the remaining tubes and move each tube back by one place in the rack after it Is logged. Save the data after each sample

11 Once ALL samples have been recorded on the shipping manifest and on the Survey Management System, transfer the EDTA (purple top), the RNA (blue top) and the Urine tubes (brown top) in the fridge. NOTE: load tubes in the rack according the SOP 'Life Study Sample Transportation'

12 After the centrifuge completed the cycle transfer the PST tube (green top) in the rack in the fridge

13 As soon as the stop watch alarm for the SST tube (orange top) goes off repeat Step 8

14 Enter the centrifuge time for the SST tube in the shipping manifest spreadsheet

15 When the centrifuge completes the cycle transfer the centrifuged SST tube (orange top) in the white rack in the fridge

a) Handling Multiple Sets of Samples

When multiple sets of samples arrive at the same time priority must be given to processing and data entry for the PST sample. Complete steps 1-9 (excluding step 4) then proceed with processing the other tubes following the order of arrival to the lab.

The same principle applies to the SST sample. When the stop watch finishes the countdown centrifuge the samples and record the time of centrifuging in the shipping manifest spreadsheet, then continue to work on the other tubes in order of arrival.

b) Recording Data for Samples Not Collected

The staff working in the Life Study Centre processing room are responsible for recording on the Survey Management System whether the sample was collected or not and the reason why, i.e. refused or failed. The reason will be indicated on the sticker attached to the ziplock or can be communicated directly by the member of staff responsible for collecting the samples.

To record that a sample was not collected:

- Find the participant on Survey Management System
- From Biosamples module select each sample that has not been collected and complete the fields:
  - *Sample collected*
  - *Reason sample was not collected.*
    Write the reason on the free text box

Staff responsible for collecting samples will record the sample s- collected and not collected- on the pregnancy visit checklist and on the ziplock bag sticker.

3.9 Preparing the Shipping Manifest

The shipping manifest spreadsheet must be sent to UK Biocentre by 5.00pm.

1. Click 'Save Workbook'
2. Save the spreadsheet with the 'save as' function and name LSC1_dd_mm_yyyy
3. Store the file in the 'Biosamples Shipping Manifest Folder'
4. Send a copy of the Shipping Manifest via email to the Life Study Biosamples Project Manager and the UK Biocentre Project Manager and team.

3.10 Appendix A

Creating a Pregnancy Sample Manifest Using Version 5.7

To create a new Pregnancy Sample Manifest, follow the following steps:

1 Version 5.7 is an Excel workbook which contains macros that need to be enabled before a new Pregnancy Sample Manifest can be created by clicking on the "Add New Sample Manifest" button (see Figure 5).

Figure 5 The front page of the Sample Manifest workbook

2 Select the date of the sample collection from the calendar

3 After the date has been selected, a new sample manifest sheet is available, and a check box asks for confirmation of the date that is required

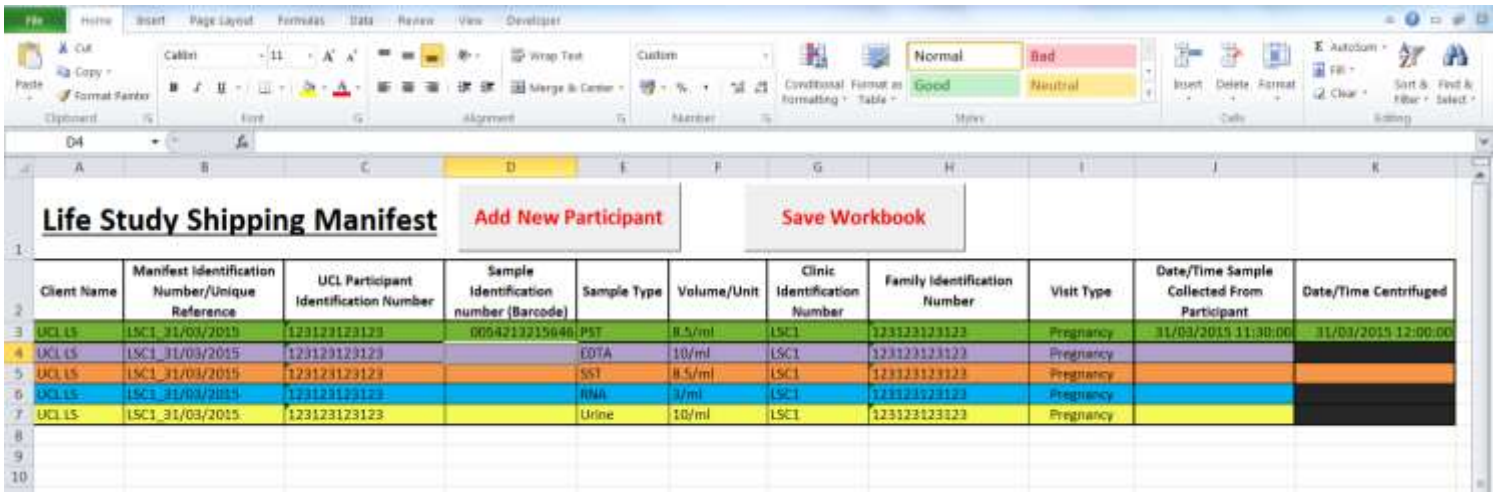
4 After confirmation of the correct date, the sample participant ID can be input

5 After the participant ID has been entered, confirm whether the FamilyID is the same as the Participant ID

6 A new Pregnancy Sample Shipping Manifest is now created (see Figure 6)

7 The blood tubes are scanned and appear in the Sample Identification number (Barcode) column.

8 The date/time the sample was collected from or by the participant should be recorded in the format of “dd/mm/yyyy hh:mm:ss” and - if required - the date and time the sample was centrifuged in the format of “dd/mm/yyyy hh:mm:ss” in the appropriate column of the Pregnancy Sample Shipping Manifest as shown in Figure 6



Life Study Shipping Manifest

Add New Participant

Save Workbook

Client Name	Manifest Identification Number/Unique Reference	UCL Participant Identification Number	Sample Identification number (Barcode)	Sample Type	Volume/Unit	Clinic Identification Number	Family Identification Number	Visit Type	Date/Time Sample Collected From Participant	Date/Time Centrifuged
UCL LS	LSC1_31/03/2015	123123123123	0004213215646	PST	8.5/ml	LSC1	123123123123	Pregnancy	31/03/2015 11:30:00	31/03/2015 12:00:00
UCL LS	LSC1_31/03/2015	123123123123		EDTA	10/ml	LSC1	123123123123	Pregnancy		
UCL LS	LSC1_31/03/2015	123123123123		SST	8.5/ml	LSC1	123123123123	Pregnancy		
UCL LS	LSC1_31/03/2015	123123123123		RNA	3/ml	LSC1	123123123123	Pregnancy		
UCL LS	LSC1_31/03/2015	123123123123		Urine	10/ml	LSC1	123123123123	Pregnancy		

Figure 6 Example of a created Pregnancy Sample Manifest

4 SOP: Preparing Samples for Transportation

DOCUMENT NUMBER: BIO037_02	**VERSION NUMBER:** v1.0
CREATION DATE: 23/04/2015 **EFFECTIVE DATE:**	**NUMBER OF PAGES:** PAGE 1 OF 3
TITLE: Preparing Samples for Transportation	**Security Classification:** Unrestricted **Criticality Classification:** HIGH

AMENDMENT RECORD

ISSUE NUMBER	DATE	CHANGE	
ORIGINATOR:	NAME: KIRSTEN WARD on behalf of Life Study Centre Biosamples Leads	SIGNED:	DATE:
CONTENT APPROVAL:	NAME: JAMES FENTON on behalf of Life Study Centre Biosamples Leads	SIGNED:	DATE:
QUALITY APPROVAL	NAME: ALEXANDRA SUFARU	SIGNED:	DATE:

This procedure is a mandatory requirement and forms part of the UK Biocentre Quality System. Amendments are only permitted via the change control procedure.

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4.1 Purpose

The purpose of this document is to describe the procedure for packaging the Life Study samples for transportation to UK Biocentre and to ensures all staff involved within the procedure do understand their tasks and responsibilities so that samples are delivered undamaged and within acceptable temperature limits.

4.2 Responsibilities

The Life Study Centre Biosamples Leads will be responsible for packaging of the samples on a daily basis, although this may at times be undertaken by other members of staff.

4.3 Definitions

Terminology	Definition
SOP	Standard Operating Procedure

4.4 Training

Training in this procedure will be achieved by reading this SOP.

4.5 Related Documents

None

4.6 Health and Safety

Gloves must always be worn when handling biological samples, and as an additional precaution, two pairs of gloves could be worn.

Do not directly lift the fully packed sample transportation box – use manual handling techniques as per internal manual handling training to move large, heavy objects safely.

4.7 Procedure

a) Preparing Samples for Transport

1 At the beginning of each day the lab technician should prepare one white sample box.

2 The Vacutainer tubes should be loaded into the white sample box throughout the day (see Figure 7)

3 Approximately 30 minutes before the courier is scheduled to arrive remove three cool packs from the freezer. Please ensure that the cool packs have been in the freezer for at least 24 hours before use.

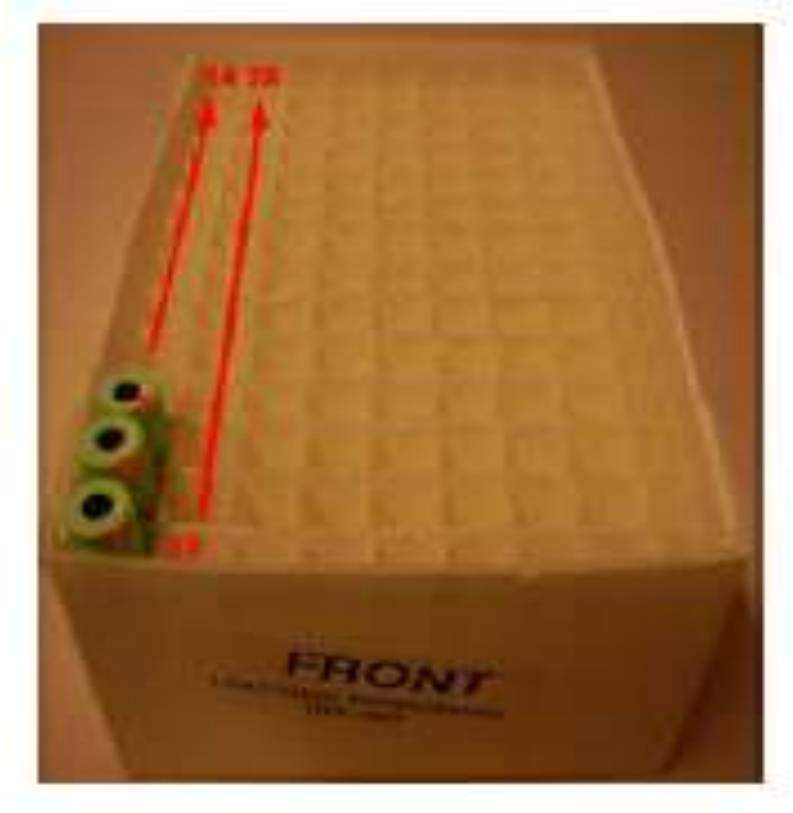

Figure 7 Sample Box

4 Put the lids on the white sample boxes and place them side by side in a clear polythene bag. Place six sheets of absorbent paper underneath each sample box, so twelve sheets in total will be within the clear polythene bag. Seal the bag with a cable tie. This only needs to be done for sample boxes which CONTAIN SAMPLES.

5 Place two cool packs and two spacers parallel to the two short sides of the large transport box. Place the bagged white sample boxes into the large transport box. To provide stability to the inner packaging it is recommended that four empty white sample boxes are placed at the bottom with the two full white sample boxes placed on top.

6 A third spacer is placed on top once the sample racks are all loaded and the third cool pack is placed on top of the spacer.

7 Close and seal the lid of the transport box with a cable tie.

NOTE: In the event that the UCL Life Study Centre staff do not adhere to their responsibilities within this procedure, the UK Biocentre management system cannot be held responsible as UCL activities are NOT covered under the scope of 9001 certification for UK Biocentre.

5 SOP: Life Study Courier Collection

DOCUMENT NUMBER: BIO037_03	**VERSION NUMBER:** v1.0
CREATION DATE: 23/04/2015 **EFFECTIVE DATE:**	**NUMBER OF PAGES:** PAGE 1 OF 4
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AMENDMENT RECORD

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This procedure is a mandatory requirement and forms part of the UK Biocentre Quality System. Amendments are only permitted via the change control procedure.

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5.1 Purpose

The purpose of this document is to describe the procedure for arranging and coordinating the sample courier between the Life Study centres and UK Biocentre and to ensure all staff involved within the procedure do understand their tasks and responsibilities.

5.2 Responsibilities

The Life Study Centre staff is responsible for liaising with UK Biocentre with regards to courier arrangements. The team at UK Biocentre will be the main point of contact for both Life Study and the courier regarding sample transportation. However on a day-to-day basis it may be appropriate for the Life Study Centre Biosample Lead are to liaise with the courier driver on occasion.

5.3 Definitions

Terminology	Definition
SOP	Standard Operating Procedure
UCL	University College London

5.4 Training

Training in this procedure will be achieved by reading this SOP.

5.5 Related Documents

None

5.6 Health and Safety

Do not lift the fully packed sample transportation box directly – use manual handling techniques as per internal manual handling training to move large, heavy objects safely.

5.7 Procedure

a) Courier Collection

1 A dedicated courier has been arranged through UK Biocentre to collect the large sample transportation box every evening, 30 minutes after the Centre closing time.

2 It is therefore important that the appointment schedule for the Centre is communicated to UK Biocentre on a weekly basis to allow the courier to be scheduled accordingly.

3 This information should be shared with the Life Study Project Manager at UK Biocentre who will coordinate the courier collections and deliveries.

4 The courier will collect the large sample transportation box directly from the Life Study Centre reception and will provide a collection receipt which must be retained and filed.

5 The samples will then be delivered to the UK Biocentre laboratory after 9 am the following morning.

6 The courier can be flexible with regards to waiting, and can wait free-of-charge for 30 minutes if for some reason there is a delay in preparing the sample transportation box. However after the first 30 minutes any waiting will be charged at an agreed hourly rate.

7 If there are no samples to be collected the courier must be informed at least 60 minutes before the scheduled collection time (which is 30 minutes after the Centre closes). This will be free of charge if it occurs on rare occasions, however if this becomes routine a 50% charge will apply.

8 In the event that the courier fails to collect the samples there are two actions to be taken:

- Contact the courier offices on <**agreed phone number**> to confirm that the courier will be coming to collect the samples and asking for the details of the driver who will be collecting the samples;
- Contact the driver who has been assigned to collect the samples to confirm that they are coming to collect the samples.

9 If the courier has still not come to collect the samples after the above actions have been taken, inform UK Biocentre by contacting the Life Study Project Manager on <agreed phone number>. Alternative arrangements will then be made with the courier for a fast-track delivery directly from the Life Study Centre to UK Biocentre.

5.8 Return of Samples Boxes from UK Biocentre to Life Study

1 Each Life Study Centre will be provided with a supply of sample transportation boxes.

2 When the courier arrives to collect the packaged samples they will also return an empty sample transportation box. So there will be a continual cycle of large sample transportation boxes.

3 Upon their return, the large sample transportation boxes must be emptied of cool packs which are then stored in the freezers within the Life Study Laboratory. Ensure that all cool packs are kept in the freezer provided, so they are ready for use.

4 If more sample transportation boxes or other equipment related to the sample shipment are required please contact the Life Study Project Manager at UK Biocentre who will arrange a delivery of these additional materials.

5.9 Temperature Monitoring

1 A temperature monitor (datalogger) should be placed inside a large sample transportation box with every shipment.

2 Before they are sent out to the Life Study Centre. UK Biocentre configures the dataloggers to begin recording automatically (when sent back, the datalogger records the time recording started).

NOTE: The Lab Technician does NOT need to press the start button. A sun symbol will be present on the datalogger screen to indicate it is set to automatically begin recording.

3 Place the datalogger on top of the rack within the plastic bag, making sure that the rack is at the top of the transport box or mediporter. This will stop the datalogger being inadvertently switched off in transit and will promote accurate recording. This should be done every time the data logger is received.

NOTE: In the event that the UCL Life Study Centre staff do not adhere to their responsibilities within this procedure, the UK Biocentre management system cannot be held responsible as UCL activities are NOT covered under the scope of 9001 certification for UK Biocentre.

6 SOP: Collection of Placentas

6.1 Purpose

The purpose of this document is to describe the procedure to collect placentas from Life Study participants who give birth at the NHS Trust linked to the first Life Study Centre.

6.2 Scope

To enable midwives and laboratory technicians to collect and handle placental specimens to the required standards of quality and safety.

6.3 Responsibilities

It is responsibility of the Life Study Midwives to oversee and ensure that the sample collection procedures are carried out in accordance with this document.

It is the responsibility of all midwives to carry out these procedures in accordance to this document.

6.4 Training

Training is provided by Life Study staff to the Life Study midwives and laboratory technicians in first instance.

Life Study midwives are responsible for organising and delivering training to community and ward midwives. Training will be also achieved by reading this SOP.

On completion of training, staff will complete and sign the Life Study training record form.

6.5 Related Documents

- Packaging and Shipment of Placental Samples SOP
- Life Study Checklist (Appendix A)
- LIFE Study Log Book (Appendix B)
- BHRUT fridge temperature checklist
- BHRUT policy for the disposal of biological substances

6.6 Health and Safety

- Wear non-sterile gloves throughout the procedure
- Dispose of residual biological substance and biohazard material according to the BHRUT procedures

6.7 Timing of Sample Collection

Samples should be collected by the attending midwife in the delivery room as soon as possible after delivery but without causing any delay or disruption to the birth or clinical processes after birth.

6.8 Equipment and Materials

- Non-sterile gloves
- Inco-pads
- Sealable placenta bags (UN3373 safety bag)
- Life Study labelling system (Personal Digital Assistant (PDA) Device) and handheld sticker printer
- Blank Life Study labels

6.9 Procedure

Before continuing with this procedure, ensure that the parents remain willing to provide the sample. Parents may decline to give the sample at this point even if consent has previously been given.

a) Check that the placenta is no longer required by the midwives and clinical staff.
b) Using the Life Study PDA printer scan the participant wristband and your staff ID badge, print one patient ID sticker and on the placenta bag.
NOTE: Stickers should be printed as close to the time of placenta delivery as possible.
c) Put on non-sterile gloves.
d) Place the placenta and onto the Inco sheet.
e) After cord blood for the Infection and Immunity Enhancement Study has been collected, place the placenta and cord into the plastic placenta bag and seal properly.
NOTE: Prior to placing the placenta into the bag, please make sure you remove the forceps and discard the Inco sheet.
f) Record whether a sample was given and whether verbal consent was obtained using the Life Study checklist kept in the woman's notes. If a sample was not obtained ensure that a reason (e.g. consent declined) is provided.

NOTE: if the placenta is not collected circle the most appropriate reason on the Life Study checklist:

Declined - the patient has declined consent
Failed - any reason that prevented the collection
Histopathology- the specimen required clinical examination

g) Place the placenta bag containing the sample into the Life Study fridge in sluice room 2 on the labour ward.
h) Complete log book in labour ward sluice room.

6.10 Transfer of Samples

Samples will be held in the Life Study refrigerator in the labour ward sluice room.

The laboratory technician will be responsible for preparing the samples for shipment to Great Ormond Street Hospital once a day Monday to Thursday following the 'Packaging and Shipment of Placental Specimens SOP'. If the fridge becomes full, midwives may call the laboratory and request that the technician transfers the samples in the shipping boxes until the pick up by the courier.

6.11 Maintenance of Equipment

a) Life Study PDA Devices

Ensure that the Life Study PDA printers are docked in their allocated docking station when not in use

The Life Study Midwives will check regularly that the devices are in good working order. Report any issue to:

The Blood Track Administrator/Support,
Blood Transfusion Service, Level 2 Pathology, Room 206024
Tel. 01708 435 000 ext. 2816

b) Life Study Fridge

The temperature of the fridge needs to be kept between 2 - 8°C.

The fridge temperature will be monitored and recorded daily on the BHRUT Daily Fridge Checklist as per local procedure.

In case of a fault immediately notify the Lab Technicians. Placental samples should be left in the fridge until the collection by the courier is due. The Life Study Midwifes and the Lab Technicians are responsible for reporting any technical issue to the Life Study team.

6.12 Appendix A

Life Study checklist – *to be used in conjunction with the Life Study log book*

Notes for maternity unit staff:

- Please complete full checklist before discharge, ensuring that a reason (e.g. consent declined) is provided if a sample is not given.
- Please check verbal consent from mothers before taking a sample.
- Midwives should collect or assist with collection of samples if required.

Kit checklist

	Action	Task completed?	Reason if task not completed
	Kits to be issued at triage reception		
1	Maternal urine kit issued	☐	
2	Maternal poo kit issued	☐	
3	Vaginal swab kit issued	☐	
	Kits to be issued on the labour ward		
4	Cord blood*	☐	
5	Baby saliva*	☐	
6	Baby urine kit issued	☐	
	Kits to be issued at discharge		
7	Baby poo kit issued	☐	

***NOTE**: These samples should be collected by midwives

Collection checklist

	Action	Task completed?	Reason if sample not collected
Samples to be stored in the Life Study fridge			
1	Maternal urine collected	☐	
2	Maternal poo collected	☐	
3	Vaginal swab collected	☐	
4	Placenta collected	☐	Declined / Failed / Histopathology
5	a. Baby urine collected *b. Faecal contamination of urine?*	☐ *Yes* ☐ *No* ☐	
5	Baby saliva swab collected	☐	
Samples to be stored at room temperature			
6	Cord blood collected: RNA (blue cap) Serum (white cap) CBMCs (orange cap)	 ☐ ☐ ☐	

Date completed _____

Signed (discharging midwife) _____

HAND THE COMPLETED CHECKLIST TO THE WARD CLERK AFTER DISCHARGE

6.13 Appendix B

Life Study Log Book

Date:

NOTE: Please write date & time that EACH individual specimen is placed in Life Study fridge OR cord blood placed in Life Study box

Blood samples ONLY to LIFE STUDY BOX, all other samples to be placed in the LIFE STUDY FRIDGE

	CORD BLOOD (LIFE STUDY BOX)			LIFE STUDY FRIDGE						
Participant Name	**Blue**	**Orange**	**White**	**Placenta**	**Vaginal Swab**	**Maternal MSU**	**Maternal Faeces**	**Baby Saliva Swab**	**Baby Urine**	**Midwife Signature**
J.DOE (Example)	08/04/15 15:00hrs	08/04/15 15:00hrs	08/04/15 15:00hrs	08/04/15 15:00hrs	07/04/15 22:00hrs	07/04/15 21:00hrs	08/04/15 13:20hrs	08/04/15 16:05hrs	08/04/15 21:58hrs	

7 SOP: Packaging and Shipment of Placentas

7.1 Purpose

The purpose of this document is to describe the procedure for packing placental specimens (WHO protocol WHO/EMC/97.3 Safe Transport of Infectious Substances and Diagnostic Specimen) and shipping the placentas from the Labour Ward to Great Ormond Street Hospital Histopathology Laboratory, to ensure they are delivered undamaged, within the acceptable temperature range and with their relevant identification data.

7.2 Responsibilities

The Life Study Medical Laboratory Assistants (MLAs) are responsible for preparing the placental specimens for the shipment, booking the collection via the Life Study Centre 1 and completing the Placentas Shipping Note for the Histopathology staff at Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH).

The MLAs and the Life Study midwives will liaise with the Labour Ward reception team and the Life Study Biosamples Project Manager to ensure that the courier service runs smoothly and report any issue or change in local operations that may impact on sample collection.

7.3 Training

Training in this procedure will be achieved through attending the practical training session and by reading this SOP.

7.4 Related Documents

- Placenta Shipping Note (Appendix A)
- Placenta Samples Shipping Note (Appendix B)
- Expected Due Date List
- Samples Log Book

7.5 Equipment

- Blue polystyrene box with lid and 2 metal rods per box
- Cool packs (2 per box)
- Clear plastic bags (one to contain two UN3373 safety placenta bags)
- Absorbent sheets
- Cable ties
- Non- sterile gloves

7.6 Health and Safety

Gloves must be worn when handling placental samples. A laboratory coat or plastic apron should also be worn.

7.7 Procedure

1 Before starting the procedure ensure that the cool packs have been refrigerated for AT LEAST 24 hours before use and that that there are at least two blue boxes and four cool packs refrigerated at all times.
NOTE: When only two blue boxes or four cool packs are left notify the Life Study Biosamples Project Manager to arrange the recycling of transport material

2 Every day from Monday to Thursday by 2.45 pm phone the Life Study Centre at BHRUT to book or cancel the collection and complete the 'Placenta Samples Courier Log for MLAs' (see Appendix B).
NOTE: The call MUST be made to confirm whether there are or aren't samples to be collected and should be made no later than 2.45 pm

3 At approximately at 4.30 pm take the placentas out of the fridge and check that each placenta bag is labelled with the Life Study sticker and that the sample is recorded in the samples Log Book.
NOTE: Samples without the Life Study label cannot be shipped and must be reported to the Life Study midwife and the Life Study Biosamples Project Manager to confirm their identity and provenance

4 Put four absorbent sheets and up to two placenta UN3373 safety bags in a clear plastic bag and close with a cable tie

5 To prepare the shipping box:
   a) Put one cool pack at the bottom of the blue box
   b) Fill the box with the clear plastic bags containing the placenta UN3373 safety bags

   NOTE: Placentas should be piled in chronological order, so that the most recent is on bottom and the oldest on top

6 Put one temperature logger plate on the samples

7 Insert two metal rods in the ridges inside the box until they are just above the samples and lay the second cool pack on the rods

8 Close the box with the lid and two cable ties

9 Take the box to the labour ward reception and remind the reception staff that the courier is expected to arrive and collect the box between 5.00 and 7.00pm

10 Using the information from the samples Log Book complete the Placenta Samples Shipping Note spreadsheet (see Appendix A)

11 Name the spreadsheet as <Hospital Name> dd_mm_yyyy and send via e-mail to the GOSH Histopathology Research Assistant using the agreed email and to the Life Study Biosamples Project Manager before 5.00 pm
12 Save the file in the 'Placentas Shipping Note' folder
NOTE: The list of Expected Due Dates (EDD) must be sent to the GOSH Histopathology Research Assistant at the beginning of each month.

7.8 Courier Service

The courier service is provided by a dedicated driver that collects samples from the Life Study Centre at BHRUT and from the Labour Ward on an 'as required basis'.

Late cancellations for one or both sites incur a cancellation fee. Therefore it is important that scheduled and unscheduled absences and/ or changes in the shift pattern that may impact on the ability to ship samples are communicated to the Life Study Centre Manager and the Life Study Biosamples Project Manager as soon as possible (i.e. at least one day in advance) in order to cancel the courier service on time to avoid the payment of the cancellation fee.

The driver will pick up the shipping box from the labour ward reception. If urgent communication is required after the collection has been booked or cancelled, call the driver and inform the Life Study Biosamples Project Manager as soon as possible of any issue or change with the collection.

7.9 Appendix A

Placenta Samples Shipping Note

Date **dd/mm/yy**

Participant name	Date of Birth	Date of delivery	Time of delivery
	dd/mm/yy	dd/mm/yy	dd/mm/yy

7.10 Appendix B

Barking, Havering and Redbridge University Hospitals NHS Trust

PLACENTA SAMPLES COURIER LOG FOR MLAS

Date	Time phoned	Booking or cancelling	Name of caller	Name of person spoken to

8 SOP: Processing of Placentas – Interim Service

8.1 Purpose

The purpose of this document is to describe the procedures for the operational management and data collection, within Great Ormond Street Hospital (GOSH) Histopathology Laboratory and related areas, for the placental specimens collected at BHRUT Labour Ward.

8.2 Responsibilities

The Histopathology Research Assistant at GOSH is responsible for all the procedures from sample receipt to sample storage. The MLAs at BHRUT are responsible for all the procedures carried to prepare and ship the specimens including their data

8.3 Training

Training in this procedure will be achieved through a practical demonstration of the operational processes and by reading this SOP.

8.4 Related Documents

- SOP 01.48 'The Handling and Dissection of Placentas for Research (Life Study)'
- Core- Birth Samples Shipping Manifest
- Placenta Samples Shipping Note
- Expected Due Date list
- Life Study Survey Management System user manual

8.5 Equipment

- 2D barcode scanner
- 2D coded cryovials and wax cassettes
- Four cryoracks
- Temperature logger reader

Laboratory equipment for samples processing is listed in the SOP Index No.: *SSOP 01.48 'The Handling and Dissection of Placentas for Research (Life Study)' pg 83.*

8.6 Health and Safety

Health and safety measures and procedures are described in the SOP Index No.: *SSOP 01.48 'The Handling and Dissection of Placentas for Research (Life Study)' on pg. 83*

8.7 Pre- Sample Processing Procedures

a) Data Entry and Preparation of Laboratory Equipment

1 Scan the barcodes of three cryovial plates (one for samples stored at -80C, one for samples stored in LN2 and one for the quality control samples) into the GOSH Life Study Placenta Sampling spreadsheet 'plate barcode' field (figure below). This is a reference and back-up database for placental samples processed at GOSH. NOTE: copy the barcode into 48 cells, one for each plate well.

	A	B	C	D	E	F	G	H
1	Placenta Barcode record:							
2								
3	Plate Well	Date/Time of data entry	Plate Barcode	Sample Barcode	Sample type	Study ID	Histology Barcode	
4	A1	24/07/2015, 10:45	SA00153685	FB00812921	-80	MAT-106135-DG17	MAT-106135^DG17^^A	
5	B1	24/07/2015, 10:46	SA00153685	FB00812922	LN	MAT-106135-DG17	MAT-106135^DG17^^B	
6	C1	24/07/2015, 10:47	SA00153685	FB00812923	QC	MAT-106135-DG17		
7	D1	24/07/2015, 10:48	SA00153685	FB00812924	GOS sample A1	MAT-106135-DG17		

2 Log on Survey Management System and find the participants that are listed in the Placenta Shipping Note. For each participant complete the following fields of the Biosamples module 'Placenta and Placenta and Membranes' sections:

- Sample collected
- Date and Time of collection (i.e. date and time of placenta delivery)
- Time sample processed/ aliquoted

NOTE: remember to save after completing each section. The Save icon is on the bottom right of the screen

3 Copy the participant study ID from Survey Management System into the 'study ID' field of the GOSH Life Study Placenta Sampling spreadsheet

4 Print the 2D barcode on two wax cassettes per each participant using the nomenclature:

- Study ID^^ A, for cord and membranes
- Study ID^^B, for placenta

5 Scan the barcode of the two wax cassettes and two cryovials into to the 'sample barcode' filed of the GOSH Life Study Placenta Sampling spreadsheet

6 Print a copy of the GOSH Life Study Placenta Sampling spreadsheet to use as a reference during sample processing

b) Quality Checks

Specimens are delivered to GOSH pathology reception area every evening from Monday to Thursday and processed the following day.

Before beginning the processing:

- Check for leakage of fluids in the box and damaged specimen bags
- Check that temperature in the box is within the range of 2°C to 10°C
- Download the temperature logger records into the Temp Log spreadsheet (system tbc)
- Check that each placenta bag has the Life Study label with the participants' details
- Check that the specimens received match the specimen in the Placentas Shipping Note

NOTE: Any issues with the actions above must be recorded on the Survey Management System under 'Sample Error' and reported to the Life Study Biosamples Project Manager

8.8 Sample Processing

Each placenta will be aliquoted into cryovials and Formalin-fixed, paraffin-embedded (FFPE) cassettes as per the table below:

	Placenta	Cord and Membranes
Cryovial	4 (8 samples*)	N/A
FFPE cassette	1 (1 sample)	1 (1 sample)

*Two samples for each cryovial. Four samples will be collected from a subset of participants for quality control

1 Aliquot the specimen following SOP 01.48 *'The Handling and Dissection of Placentas for Research (Life Study)' pg.83.*

NOTE: Begin with the specimen with the oldest delivery date and keep the other specimens inside the shipping box with the cool packs until they are processed

2 Record the aliquots on the Birth Samples Shipping Manifest spreadsheet:

- Click on 'New Core Birth Manifest'
- Using the printed copy of the GOSH Life Study Placenta Sampling spreadsheet as a reference enter the participants' study ID and scan

barcodes of the racks, the cryovials and wax cassettes into their respective fields (-80°C; LN2; QC).
NOTE: the racks are scanned into the shipping manifest ONLY ONCE when a new rack is started

3 Save the Birth Samples Shipping Manifest in the shared drive and send a copy to d.viscusi@ucl.ac.uk every Friday. The Birth Samples Shipping Manifest will be sent to UK Biocentre along with the shipment of frozen samples for long term storage

8.9 Sample Storage

Samples are stored at GOSH Histopathology Laboratory until full capacity is reached and transferred to UK Biocentre for long term storage. Short and long term storage is arranged as per table below:

	GOSH	UK Biocentre
Minus 80°C	4 cryovials*	2 cryovials
Liquid Nitrogen	N/A	1 cryovial
Room Temperature	2 FFPE cassettes	2 FFPE cassettes

* Two cryovials will contain samples collected from a subset of participants for quality control. One of which will be retained at GOSH and one will be sent to UK Biocentre

9 SOP: The Handling and Dissection of Placentas for Research

Department of Histopathology Great Ormond Street Hospital for Children NHS Foundation Trust		
Prepared by: A Virasami	**Authorised by : N.J Sebire**	**SOP Index No. : SSOP 01.48**
Start date: September 2014	**Review date: 2 years**	**Page 41**
Area of application:	**ROUTINE HISTOPATHOLOGY – all Research staff**	

SOP title: The Handling and Dissection of Placentas for Research (Life Study)

9.1 Purpose

Whole placentas and cord are received from BHRUT via courier. These must be sampled promptly and appropriately recorded. The Life Study requires samples to be refrigerated during transit, and upon delivery to Histopathology (between 2-6°C). All placentas must be sampled in a well-ventilated area.

9.2 Material

- Macroknife
- .22 Scalpel blades
- Forceps
- Scissors
- Cutting board
- Weighing scale
- Camera
- Camera mount
- Tin foil
- Cryovial
- Tissue Cassettes
- Freezing station
- 10% Formal Saline
- Yellow WIVA bin

9.3 Risk Assessments

Please refer to policy **SRA031**

9.4 Safety Considerations

Appropriate Personal Protection must be worn at all times. Avoid inter-sample contamination by disinfecting all equipment between placentas. Please refer to **SRA031** for specific safety considerations.

9.5 Quality Control

If there are any suspicious lesions, or gross abnormality these must be photographed and sampled histologically. Quality Control is carried out by Royal College of Pathologists Registered Pathologist. If there is an issue with the receipt/transport of the sample, the courier must be informed as well as the reporting pathologist. A note must be made of any inadequate handling.

9.6 Method

1 Samples are to be booked in, with Hospital number, date/time of delivery, time of sampling and unique Participant ID.

2 Data are to be entered systematically, before the placenta has been cut.

3 Take a photograph of fetal, maternal and cut surfaces.
Place unique Participant ID in each of the pictures for future identification.
Ensure photo dimensions are consistent by using a camera mount. See **SSOP 01.22**.

4 Take measurements of the placenta and cord dimensions:
- Three measurements per placenta: height, width and depth in centimetres
- Measure cord length and cross section width in centimetres.

5 Weight (whole and trimmed).
Drain the placenta of excess blood, and weigh. Record weight in grams.

Trim off umbilical cord at the base, and remove inverted membrane. Take care not to remove membrane covering the fetal surface. Record this trimmed weight in grams.

6 Sample the umbilical cord and membrane

Take a 5mm transverse section of representative umbilical cord (plus any lesions as necessary – photograph if unsure). Cut a 1cm ring of entire membrane at the delivery site and sample, plus an additional strip of membrane from delivery site to placental surface.

7 Serially slice the placenta

The unfixed placenta should be sliced with a clean, sharp macroknife in 1cm increments. Cut from the fetal side, starting from the outside right edge.

From these slices, identify any 'lesions' and photograph if necessary. Take two full thickness sections of normal placenta (from fetal to maternal surface, up to 2cm in width) as well as a full thickness section of any lesion.

From the area immediately adjacent to the normal full thickness section (mirror block) take 0.5cm cubes of tissue from the middle of the placental parenchyma, avoiding the maternal and fetal surfaces, for:

- DNA
- RNA
- Proteomics
- Pollutants

8 Freezing of Tissues (SSOP 10.02)

Wrap at least 4 individual cubes of placental parenchyma in separate foil packets, with ID. Take care to remove pockets of air. Snap-freeze by placing into chilled hexane (or liquid nitrogen) for 10 seconds or more. Store at -80°C in cryovials immediately. Record freezer location.

9 Sections for Histology: **SSOP 01.11, SSOP 01.12, SSOP 01.13, SSOP 01.14, SSOP 01.15**

- Formalin fix the full thickness sections in cassettes for at least 24-48hrs.
- Process and embed in paraffin wax.
- Cut sections at 3µm.
- Stain with Haematoxylin & Eosin.

10 Storage of Photographs

Systematically transfer images of placentas to a secure file location. Retain unique ID as folder name.

11 Disposal of placenta

Submerge the placenta in 10% formal saline. Leave for seven days to fix thoroughly. Dispose via incineration.

9.7 Control of Substances Hazardous to Health (COSHH)

Substance	Location	Safety Information
10% Formal saline	Specimen reception, booking-in bay.	Please see safety data sheet in COSHH folder.
Hexane	Specimen reception, flammable cabinet.	Please see safety data sheet in COSHH folder.
1% TRIgene	Specimen reception, dissection bay.	Please see safety data sheet in COSHH folder.

10 SOP: Collection of Infant Urine at 6 and 12 months

NOTE: The Life Study SOP: Collection of Infant Urine were not finalised or implemented, as Life Study funding was withdrawn by the funders in October 2015 before the infant visits had commenced.

10.1 Purpose

The purpose of this document is to describe the procedure to collect and process urine samples from infants attending the 6 and 12 month appointments and to ensure staff

10.2 Responsibilities

Life Study Centre staff are responsible for collecting and processing baby urine samples. The Centre Manager will ensure that all staff will work in accordance with this SOP.

10.3 Consent

Before continuing with this procedure ensure that consent has been obtained from the parent. Please make it clear that participants will not receive any results regarding their urine sample in line with the information provided in the participant information sheet and Life Study Ethics and Governance Framework.

10.4 Equipment

- Three (medium sized) cotton wool balls or cotton flat pads
- 20 ml syringe
- Disposable Nitrile gloves
- Screw top specimen container for urine sample
- Sealable plastic specimen bags

10.5 Procedure

1 Pre-prepare urine collection kits to hand to mothers: place three cotton wool balls or cotton flat pad into a sealable specimen bag (large enough for a nappy).

2 As you prepare to give a kit to a parent, place a participant's barcode onto the specimen bag.

3 Explain the procedure to the parent, and give them the urine collection kit and let them know where baby changing facilities are located.

4 Ask the parent to carefully place 3 cotton-wool balls or cotton flat pad just in front of the genital region in their baby's nappy. The nappy should be clean

when the cotton wool or pad is positioned, that is, either a fresh nappy used or the one currently being worn providing the baby has not already passed urine or faeces. The nappy should be fastened as normal.

5 The nappy will need to be taken off when the baby is weighed and this will happen towards the end of the clinic visit. If the baby has passed urine by that stage, then the nappy can be placed in the sealable bag and put to one side at that time. Alternatively if the baby needs to be changed before then, the mother can change the baby, place the dirty nappy with the urine soaked cotton wool balls or cotton flat pad in the sealable bag, and give it to the researcher.

6 If the cotton-wool or cotton flat pad is heavily contaminated with faeces the parent should discard the contaminated cotton wool or pad and ask for fresh cotton wool balls or pad (depending on their anticipated remaining time in the Centre). If only some of the cotton-wool balls are contaminated with faeces, then these should be discarded, but urine can still be extracted from the remaining cotton-wool balls.

a) Extraction of Urine from the Cotton Wool

1 Take the nappy containing the wet cotton wool balls or pad into the dirty utility room

2 Remove the plunger from a 20ml syringe

3 Wearing gloves, carefully place the cotton-wool balls in the barrel of the syringe.

4 Replace the syringe plunger into the barrel of the syringe and depress to squeeze the urine out of the cotton wool into a urine specimen container. Once as much urine as possible has been squeezed out, screw the cap on the specimen container and ensure it is tightly secured.

5 Dispose of the nappy, dirty specimen bag, syringe, cotton-wool balls and gloves in a clinical waste bin

6 Label the urine specimen container carefully with participant details, then place it into a clean specimen bag and seal it.

7 Take the sample to the laboratory processing room for preparation for transport and collection.

b) Data Collection

1 In the Life Study Survey Management System record whether a urine sample was obtained or not.

2 Record whether there was any faecal contamination of the urine sample.

11 Participant Withdrawal

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11.1 Purpose

The purpose of this procedure is to detail the correct method to action and confirm the withdrawal of Life Study participants' information from the UK Biocentre systems to ensure the destruction of the associated samples.

11.2 Scope

Enables UK Biocentre staff to destroy safely and to required quality standards the biological samples and related data of the Life Study participants who have withdrawn from the study. It ensures that the wishes of the Life Study participant are upheld and that all associated samples and information on the UK Biocentre systems is removed.

11.3 Responsibilities

Life Study is responsible for ensuring that all staff and NHS staff collaborating with the Study are aware of and follow the procedure set out in this SOP to record participants' withdrawal from donation or retention of biosamples and communicate this to the Life Study Biosamples Project Manager.

All laboratory staff at UK Biocentre will be responsible for carrying out this procedure. The UK Biocentre Project Manager will oversee that all laboratory staff will work in accordance with this document.

11.4 Definitions

Terminology	Definition
SOP	Standard Operating Procedure
LIMS	Laboratory Information Management System
UCL	University College London
PM	Project Manager

11.5 Training

Training in this procedure will be provided by the Life study centre manager and will be achieved by reading this SOP.

11.6 Procedure

1 On receipt of verbal or written instructions by a participant who has provided a biosample that they wish to withdraw their (or in the case of an infant for whom they have legal parental responsibility, their child's) biosamples from Life Study, the Life Study Biosamples PM will notify the UK Biocentre PM with the relevant participant ID.

2 Following receipt of this notification, the UK Biocentre PM will liaise with the UK Biocentre Laboratory Manager and LIMS team to identify all of the information contained within LIMS for this participant and the location of all of the samples and aliquots that are stored for this participant.

3 Before action is taken, the UK Biocentre PM will liaise with the Life Study Biosamples PM to obtain confirmation from Life Study that the correct participant and all of the aliquots and samples that are stored for that participant have been identified.

NOTE: Samples that are part of a withdrawal and destruction request cannot be picked and destroyed unless this confirmation has been received.

4 Once confirmation of the participant to be withdrawn is received, the UK Biocentre PM will inform the laboratory manager who will instruct a member of the laboratory team to pick the aliquots and samples to be destroyed.

5 An independent member of the laboratory team will cross check the samples against the destruction list that has been produced and confirmed by the UCL and UK Biocentre PM's.

6 After the destruction of the aliquots and samples, the laboratory team member is to inform the UK Biocentre PM, Laboratory Manager and LIMS team that the samples have been destroyed.

7 The UK Biocentre PM confirms the destruction of the aliquots and samples with Life Study Biosamples PM by providing a list of the samples that were successfully picked and destroyed. If there were samples on the list that were not destroyed, the UK Biocentre PM must provide the Life Study Biosamples PM with an explanation.