

STANDARD OPERATING PROCEDURE FOR Management of Pregnancy Loss Remains (under 24 week's gestation) from Early Pregnancy Unit & Gynae at RGH, PCH & POW CONTROL SHEET

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Location of copies	<i>Early Pregnancy Unit & Gynae at RGH, PCH & POW</i>		
Responsibility	Any suitably trained member of staff can perform this procedure. Trainees can perform this procedure with supervision.		

Section reference	Details of change	Date change implemented	Authorised by

Details of modifications to this SOP must be authorised by the HTA Designated individual

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1. PRINCIPLES OF THE PROCEDURE.

This standard operating procedure outlines the correct process for the completion of the Consent for respectful disposal of pregnancy loss remains under 24 weeks gestation, the Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains and the process for transferring pregnancy loss remains to the Mortuary department.

This document is informed by CTMUHB Policy for the sensitive disposal of pregnancy remains (PATH 02), the policy upholds the guidelines set out by The Royal College of Nursing, the Still birth and Neonatal Death Society (SANDS), The Human Tissue Authority (HTA) and the Institute of Cemetery & Crematorium Management (ICCM). It also complies with the Equality Act 2010.

This document aims to ensure that all pregnancy remains of less than 24 weeks gestation resulting from all circumstances of loss of pregnancy, are processed of in a sensitive, dignified manner and transferred to the mortuary with the required traceability. Throughout this document the term patient is used and represents mother's / clients. The shortened version is used for ease of reading

2. RESPONSIBILITIES

Person Designated named on the HTA licence, supplementary to the DI in the governance framework. This person will often act at a local level to support the DI.

Persons Designate for Early Pregnancy Unit & Gynae at RGH, PCH & POW;

- Ensure staff aware of this standard operating procedure
- All staff performing this procedure are trained
- Training records for this procedure are maintained
- Updates to this procedure are disseminated to staff
- DATIX arising from non conformities of this standard operating procedures and investigated and corrective action plans are implemented and monitored
- Actions and findings arising from Audit arrangements are completed

Staff performing this procedure;

- All staff are expected to comply with this operating procedure
- Staff performing this procedure are required to have read and understood this SOP.

3. PROCEDURE

3.1 Completion of the *Consent for respectful disposal of pregnancy loss remains under 24 weeks gestation form*

- 3.1.1 This form enables the patient to consent for the respectful disposal of pregnancy remains delivered before the 24th week of gestation.
- 3.1.2 The *Consent for respectful disposal of pregnancy loss remains under 24 weeks gestation form* (Consent form) (Appendix 1) must be completed by the patient.
- 3.1.3 In the event the Consent form cannot be completed by the patient the health care professional completing the *Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form* may complete the consent form on the patients behalf after discussing the available options with the patient
- 3.1.4 The following groups are responsible for completing the *Consent for respectful disposal of pregnancy loss remains under 24 weeks gestation form* with the patient;
- PCH Gynae ward – Nursing staff and/or medical team
 - PCH EPU – Nursing staff and/or medical team
 - POW EPU – Nursing staff and/or medical team
 - POW Gynae ward – Nursing staff and/or medical team
 - RGH – Nursing staff and/or medical team
- 3.1.5 It is best practice to complete the Consent form prior to any medical intervention
- 3.1.6 In-order for the patient to provide **informed consent** for their chosen disposal option the patient must have;
- Been provided with and given the opportunity to read the supporting information booklet titled, ***“Your choices following pregnancy loss”*** (Appendix 2)
OR
 - Discussed each option candidly with a Health care professional and;
 - Been given the opportunity to ask questions about the disposal options.
- 3.1.7 The patient must be asked to initial the first section of the Consent form to denote they have been provided the above opportunity
- 3.1.8 The patient must then initial ONE disposal option and complete any other related field.
- 3.1.9 The patient must then complete the section titled, ***Details of person giving consent***
- 3.1.10 The remaining form fields must be completed in full by the health care professional

NB: Failure to properly complete this form may result in a delay to the disposal and/or investigation of the pregnancy loss. All non-conformities will be DATIX

3.2 Completion of the Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form

- 3.2.1 The *Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form* (Certificate) can only be completed by a registered midwife, nurse or medical practitioner
- 3.2.2 The Certificate is a requirement under the Institute of Cemetery & Crematorium Management (ICCM) Regulations and denotes that the Pregnancy loss remains are **not** a stillbirth or neo-natal death
- 3.2.3 All sections of the form must be printed and clearly legible
- 3.2.4 The Notification of further investigation section must be **INITIALED** by the completing health care professional. Any request for further investigation must be accompanied by the relevant investigation request documents.
- 3.2.5 The following groups are responsible for completing the *Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form*
- PCH Gynae ward – Nursing staff and/or medical team
 - PCH EPU – Nursing staff and/or medical team
 - POW EPU – Nursing staff and/or medical team
 - POW Gynae ward –Medical team, Nursing staff and/or Gynae Midwifery Practitioner
 - RGH – Nursing staff and/or medical team
- 3.2.6 It is best practice for the responsible clinician or practitioner to complete the *Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form* (Certificate) immediately after examination of the pregnancy loss remains
- 3.2.7 The Notification of further investigation section should be completed after discussion with the patient

3.3 Preparing the remains for transfer to the Mortuary

Preparation of the pregnancy remains should be prepared as soon as possible after delivery. This section is informed by Mortuary Service SOP MPRA Pregnancy loss remains – Transfer and admission to the Mortuary Service

- 3.3.1 **Do NOT** add Formalin, Saline or any other fluid as this may interfere with further investigations if required
- 3.3.2 All blankets, toys and/or keepsakes must be placed in a sealed plastic bag and labelled with the patient's information.

Under 20 week's gestation

- 3.3.3 Pregnancy remains must be delivered in a sealed opaque container with a secure lid. These containers can be sourced from the Cellular pathology department
- 3.3.4 Patient demographic information must be affixed to the container **and not the container lid**
- 3.3.5 Patient demographic information affixed to consent forms and PLR containers must at the very minimum comprise of the following;
 - Full name of mother
 - Address
 - Date of birth
- 3.3.6 PLR's are to arrive at the mortuary with;
 - A Completed Consent for respectful disposal form,
 - A Completed Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form and;
 - Any further investigation request forms

NB: All non-conformities to the standards outlined in Sections 2.4 will be recorded via Datix against the department where the pregnancy loss was generated.

Between 20 weeks and 23+6 weeks gestation

- 3.3.7 Later pregnancy losses where a discernible fetus is present, may be transported to the mortuary department in a basinet.
- 3.3.8 Affix an identity bracelet to the baby (leg or waist). Identity bracelets must not be placed on clothing or accompanying basinet as this carries risk of dislodge and unidentification
- 3.3.9 Baby should be wrapped in a cotton sheet and placed in a basinet
- 3.3.10 Where further investigation is required the Placenta must accompany the baby. This must be placed in a sealed opaque container with a watertight lid and labelled as per 2.4.4

3.4 Completing the Clinical area PLR Register

- 3.4.1 In-order to ensure full traceability of the pregnancy loss, Record the loss into the clinical PLR register.
- 3.4.2 The Clinical PLR register is located at;
- PCH Gynae ward – ward utility room
 - PCH EPU – clinical area
 - POW Gynae ward – Gynae assessment room
 - POW EPU – EPU office
 - RGH - designated cupboard in sluice
- 3.4.3 Ensure to complete the register in full including exact dates and times

3.5 Transfer to the Mortuary

- 3.5.1 Pregnancy remains must be transported to the Mortuary in the Purple PLR transfer carrier which can be located at;
- PCH Gynae ward – ward utility room
 - PCH EPU – clinical area
 - POW Gynae ward – Gynae assessment room
 - POW EPU – EPU office
 - RGH - designated cupboard in sluice
- 3.5.2 Registered Nurses staff are responsible for the transfer of pregnancy loss remains from clinical areas to the mortuary and the completion of the Mortuary PLR register
- 3.5.3 Mortuary staff must be made aware of any known risk of infection.
- 3.5.4 Porters are not permitted to transport pregnancy loss remains. Porters will escort and allow access to the mortuary out of hours;
- Weekdays: 1601hrs – 0759hrs Monday to Thursday
 - Weekends: 1601hrs Friday to 0759hrs Monday
 - Bank holidays
- 3.5.5 During the standard mortuary working hours of 0800hrs to 1600hrs, it is the responsibility of the mortuary staff to allow access.
- 3.5.6 Pregnancy Loss remains are stored in the mortuary within the **Pregnancy loss remains fridge** and must NEVER be deposited into an adult fridge.

3.6 Completing the Mortuary PLR Register

- 3.6.1 To complete the traceability record the Mortuary PLR Register must be completed by the clinical staff responsible for taking the remains to the mortuary.
- 3.6.2 The Mortuary PLR register (purple register) can be located at;
- PCH Mortuary – Body stores next to the PLR fridge
 - POW Mortuary – Body stores on top of PLR fridge
 - RGH Mortuary – Body stores bottom shelf of booking in desk
- 3.6.3 Ensure to complete the Mortuary PLR Register in full including exact dates and times that correspond with the information recorded in the local Clinical PLR Register.
- 3.6.4 Where a separate and discernible Placenta is also present, record on a new row in the Mortuary PLR register and label;
- The PLR as “A”
 - The placenta as “B”

4. Further investigation

4.1 Histology

- 4.1.1 Pregnancy loss remains requiring Histology investigation must be accompanied by a cellular pathology request form (Histology form) and be transported to the mortuary as per 2.4.

Pregnancy loss remains requiring Histology investigation MUST NOT be sent directly to cellular pathology

- 4.1.2 Patient consent for their surgical procedure and / or any resultant histological examination request is the responsibility of the clinical team and is separate and distinct from the consent required for sensitive disposal of pregnancy remains.
- 4.1.3 Cellular pathology request forms accompanying such specimens should include the specimen type, the examination required and the supporting clinical details.
- 4.1.4 The cellular pathology laboratory is only to be sent gestational material for histology investigation under two circumstances:
- ERPC or tubal ectopics where the purpose is to confirm the presence of gestational material.
 - Gestational material where there is a genuine suspicion of molar pregnancy or trophoblastic disease.
- 4.1.5 There are differences in the disposal of 'pregnancy remains' and 'fetal remains' which the mother / client should be made aware of:
- 1.If fetal parts are detected in a histology sample, all preparations (blocks and slides) which may contain the remains are retrieved and sent for sensitive disposal.
 - 2.If fetal parts are not detected in a histology sample then the HTA state that preparations for pregnancy remains are considered as part of the womans / clients diagnostic record and should remain as such. Therefore, only 'left over' (residual) wet tissue which is not used for the diagnostic process will be sensitively disposed. If there is no tissue left over, there will be no tissue to sensitively dispose of. This difference is important and the care team should inform the mother / client of this so she has realistic expectations, particularly where she has opted for return of tissue to herself.
- 4.1.6 All histology wet tissues have to be retained for 4 weeks post authorisation so pregnancy remains having histology investigation will not enter the sensitive disposal pathway until much later than pregnancy remains for direct sensitive disposal i.e may miss the next scheduled cremation.
- 4.1.7 Where there are multiple remains sent to mortuary and possible referred to cellular pathology from one loss, all efforts will be made to reunite tissue for a single disposal however this may not be possible if the cellular pathology process is lengthy. The mother / client may need to be aware of this if planning to attend memorial services etc. and it will be the responsibility of the care team to discuss it with her.

4.2 Cytogenetic

- 4.2.1 The Regional Cytogenetics Laboratory for Wales provides a comprehensive cytogenetics service for the Welsh population of almost 3 million people. It is housed in the University Hospital; Wales Site, Cardiff. The tests allow detection of chromosome abnormalities which cause serious malformation syndromes, developmental delay and other disorders.
- 4.2.2 Clinical areas are responsible for the sampling of pregnancy remains and completion of the request form. Samples sent for cytogenetic testing are completely processed during the procedure and therefore no remains will be returned to the mortuary.

Sample Requirements

- 4.2.3 Samples for cytogenetic testing must have been taken at the clinical ward area. Clinicians requiring further information on ample requirements should be directed to;

<https://medicalgenomicswales.co.uk/index.php/health-professional-information/sending-samples#Postmortem>

- 4.2.4 Samples must be accompanied by a completed purple "**Laboratory Genetics Service for Wales**" form
- 4.2.5 Sample containers and request forms must be labelled in accordance with the Request form and sample labelling policy QMS020;
- Mother's hospital number or NHS number, AND
 - Mother's name (Surname and first name – not initial), AND
 - Mother's date of birth
- 4.2.6 Sampling **can only** be undertaken by medical staff
- 4.2.7 The requirements for the sample is outlined by the medical genomics wales service user guide as follows;
- The sample must be approximately 1ml (5p piece) in size,
 - Unfixed, immersed in saline or culture medium, and;
 - contained in a sealed leak-proof, standard sized universal container

N.B: Fixation of the tissue in formalin is not permitted for this investigation.

- 4.2.8 **Cytogenetic Samples are classed as URGENT SAMPLES and must be actioned for transport ASAP**
- 4.2.9 The remaining pregnancy loss remain is also transported to the mortuary as outlined in Section 3

4.3 Fetal Post Mortem

- 4.3.1 Post-mortem investigations on pregnancy remains are not performed at any site within Cwm Taf Morgannwg UHB.
- 4.3.2 Any pregnancy remains requiring an autopsy is referred from the mortuary departments to the Fetal Pathology Unit (FPU) within the mortuary at the University Hospital of Wales (UHW), Cardiff via the Mortuary department
- 4.3.3 Fetal pathology undertakes the investigation of non-viable foetuses where the mother's gestational age at delivery is less than 24 weeks and where the fetus has shown no evidence of life at delivery.
- 4.3.4 In order to comply with the HTA Guidance on the disposal of pregnancy remains following pregnancy loss or termination, all pregnancy loss remains requiring post mortem investigation must be accompanied by;
- an ***All Wales Consent to a Hospital Post Mortem Examination on a Baby or Child form*** and
 - The University Hospital of Wales "***Request for fetal, perinatal or infant post mortem examination***" form

Those health care professionals completing the form must be trained and competent and listed on the UHW consent takers database

4.4 Further investigation of Placentas (ONLY)

- 4.4.1 Where a patient has declined a Post Mortem examination of their pregnancy loss they may be offered an examination of the placental remains
- 4.4.2 Complete a Placental examination request form and ensure this accompanies the *Consent for respectful disposal of Pregnancy Loss Remains under 24 weeks gestation form* and the placenta to the Mortuary department.

4.5 Placentas with NO investigation

- 4.5.1 Where a placenta does not need to accompany a fetus for post mortem examination or require a separate placental examination then the placental tissue must be disposed of at ward area via the local area policies.

5. IDENTIFIED POTENTIAL HAZARDS

- Porter not available out of hours
- Staff not able to leave clinical area
- Misidentification
- Biohazards

6. TRAINING

Qualification of training and competence Name:		Date when completed
1	Locate policy and SOP(s) to provide this training <ul style="list-style-type: none"> • PATH 02 • Management of Pregnancy Loss Remains (under 24 week's gestation) from Early Pregnancy Unit & Gynae at RGH, PCH & POW	
2	Give a brief overview, including the following: <ul style="list-style-type: none"> • Lay out of working environment where appropriate • Location of equipment • Health and safety requirements 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Explain to the trainee that pregnancy loss remains <24 weeks are treated with the same dignity and sensitivity as a baby / child / adult body. Using the policy for sensitive disposal, explain why.	<input type="checkbox"/>
4	Explain the process of transfer and admission to the mortuary	
5	Show the Consent for respectful disposal of pregnancy loss remains under 24 weeks gestation form and explain how and why it must be completed fully and correctly. Ensure the trainee is clearly informed that forms with incorrect/ incomplete/ illegible data must be reported via DATIX.	<input type="checkbox"/> <input type="checkbox"/>
6	Show the "Your choices following pregnancy loss" booklet and ensure the trainee has read and understand the disposal options	<input type="checkbox"/>
7	Show the Completion of the Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains form and explain how and why it must be completed fully and correctly. Ensure the trainee is clearly informed that forms with incorrect/ incomplete/ illegible data must be reported via DATIX.	<input type="checkbox"/> <input type="checkbox"/>
8	Explain the procedure for placentas that enter the mortuary.	
9	Observe the trainee performing the demonstrated training	
10	Explain that any non conformities or issues must be reported as a DATIX at the soonest opportunity and that they will be reviewed by the DI.	
11	Explain the types of HTARI that may be discovered during this procedure and that they must also be reported to a PD or the DI at the soonest opportunity.	
12	Explain that ONLY staff who have received the All Wales Consent to a Hospital Post Mortem Examination on a Baby or Child may take consent for post mortem	
Trainer name: _____		Signature: _____
Trainer name: _____		Date: _____
Trainee name: _____		Signature: _____
Trainee name: _____		Date: _____

7. APPENDICES

7.1 Appendix 1 - Consent for respectful disposal of pregnancy loss remains under 24 weeks gestation form & PART B: Certificate of Midwife/Nurse Practitioner or Medical Practitioner in Respect of Pregnancy Remains

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7.2 Appendix 2 - Practical arrangements following a pregnancy loss under 24 weeks

[Practical arrangements following a pregnancy loss under 24 weeks](#)