

POLICY FOR THE SENSITIVE DISPOSAL OF FETAL REMAINS (up to 16 weeks gestation)

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Trust Lead:	Caroline Whiteley, Deputy Service Manager and HTA Designated Individual
Board Director Lead:	Andrew Furlong, Medical Director and UHL HTA Corporate Licence Holder
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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

April 2023

- Minor changes to text, spelling and grammar
- Section 4.3, 4.6 and 5.8.11 - update to responsibilities of histology and bereavement staff in relation to return of tissue to patients
- Section 5.4.2 – new Pregnancy Loss form details.
- Section 5.5.2 – details of how complete patient details should be provided to the mortuary to enable electronic record registration
- Section 5.6 – extended to include specific details of how fetal tissue should/should not be transported between clinical areas (action following incident W402886)
- Section 5.8.6 – clarification of when incidents are raised
- Updates to contact numbers and email addresses
- Removal of reference to ILAB as the specific histology and mortuary patient database
- Updates to cytogenetic information to reflect changes in testing technology (microarray rather than karyotyping)
- Replace Home Arrangement with Own Arrangement throughout
- 5.12.3 - new pregnancy loss form can be used instead of 3 part non-viable fetal burial form.
- Include reference to electronic registration of pregnancy loss samples in the mortuary
- Appendix 1, Out of Hours Release process updated – new pregnancy loss form can be used instead of 3 part non-viable fetal burial form.
- Appendix 5 – changed to more appropriate title

KEY WORDS

Pregnancy loss

Fetal remains

Communal cremation

Home / Own arrangement

Incineration

Miscarriage

Termination of pregnancy

Consent

Summary of Policy for the sensitive disposal of fetal remains (up to 16 weeks gestation) –

All fetal remains, irrespective of origin, will be handled in a respectful and dignified manner:

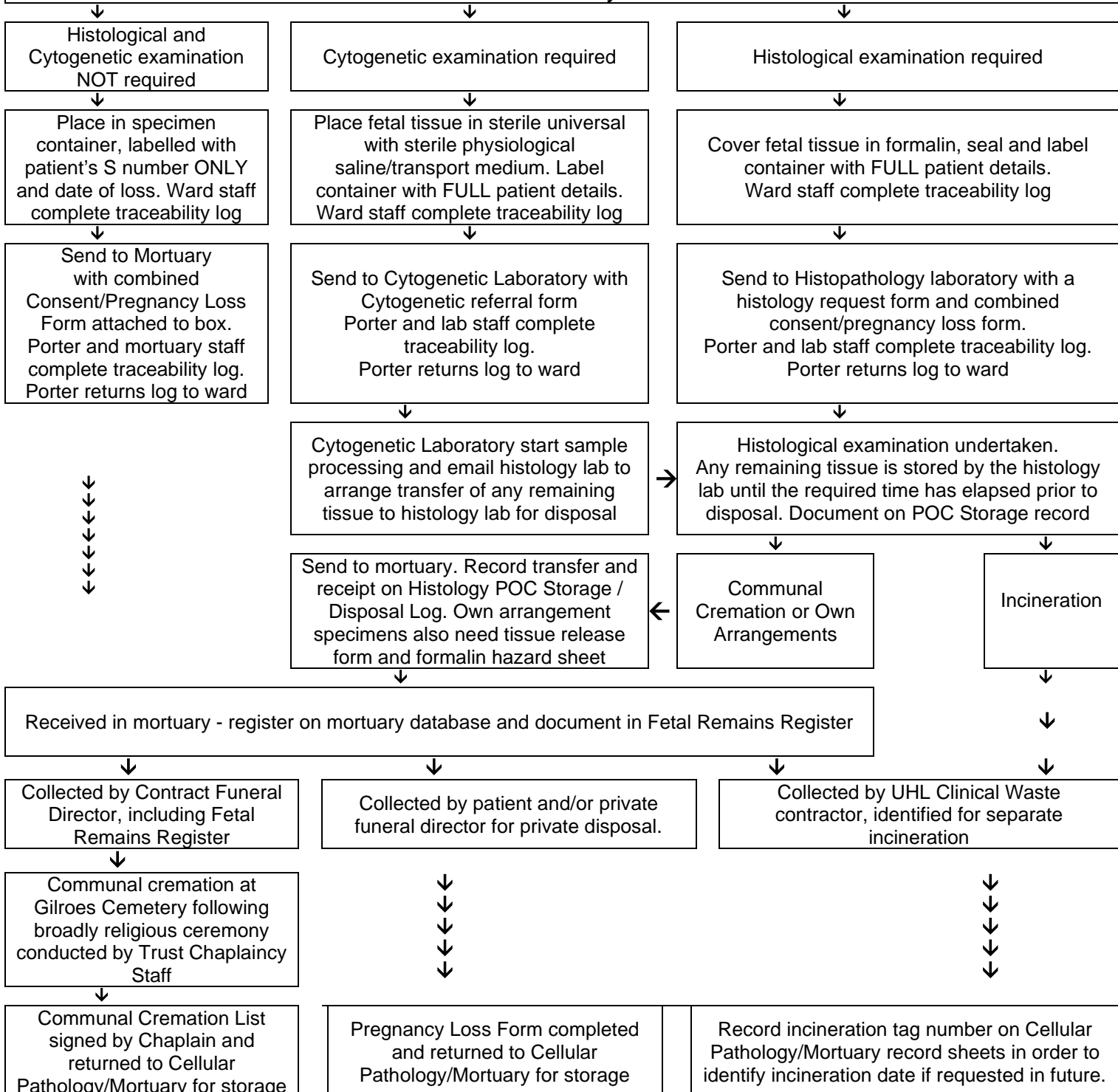
Fetal tissue will ONLY be disposed of as clinical waste if this is the express wish of the woman.
 Fetal tissue will go to the Histopathology lab (part of Cellular Pathology), Cytogenetics or the Mortuary, only in *exceptional* cases will fetal tissue be released directly from the ward;
 All fetal tissue will be handled with respect and where it is requested / required, cremated with dignity.

Fetal Loss 16 weeks or less:

(including tissue passed spontaneously, medical or surgical termination of pregnancy, salpingectomy, multifetal pregnancy reduction in early pregnancy)

Patient made aware and offered information about the hospitals policy including the disposal methods available. Patient also made aware that if they wish to decline this information and not be involved or know about the disposal process this will be respected. Patient asked to sign a consent form for examination by pathology (Histology and/or Cytogenetics) if appropriate and disposal of fetal tissue accordingly.

Histology does NOT include examination of any fetus – if this is clinically required or requested by the family refer to UHL Post Mortem Policy – see Section 5.8.3



1 INTRODUCTION & OVERVIEW

- 1.1** Pregnancy ends for a variety of reasons. Although the majority end with the birth of a live baby many women experience early pregnancy loss as a result of miscarriage, termination of pregnancy or ectopic pregnancy, and history of gestational trophoblastic disease.
- 1.2** Historically hospitals throughout England have had an inconsistent approach to the management of fetal remains following early pregnancy loss; the standard practice has been to incinerate fetal tissue along with clinical waste. This practice, whilst perfectly legal, was felt to be unacceptable and more sensitive and dignified methods of disposal were established in line with updated Royal College of Nursing guidance.
- 1.3** The Human Tissue Act 2004 has also established a legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. The Human Tissue Authority (HTA) is the regulatory body for all issues concerning this matter. While products of conception (POC) are legally maternal tissue and therefore require no specific consent for disposal, HTA best practice indicates that the same principles should be applied as are applied to tissue retained at post mortem i.e. examination and disposal require specific consent.
- 1.4** It is important that UHL has a standardised approach to the sensitive disposal of all fetal tissue (also known as products of conception) irrespective of the manner of pregnancy loss before the 16th week of pregnancy. This will meet the requirements of the Human Tissue Authority, as well as minimising potential distress caused by unclear procedures at this difficult time.
- 1.5** This policy is endorsed by the UHL Ethics Committee. This policy refers solely to the patient, reflecting her unique statutory rights and privileges, and does not apply to any other aspect of fetal loss other than the disposal of fetal tissue.
- 1.6** Standard procedures have been established for the handling and disposal of fetal tissue. Full details are found in the relevant sections and appendices of the policy as referenced. Individual areas that require specific procedures for handling fetal specimens should draw them up in line with the procedures detailed in this overarching policy.
- 1.7** It is the belief of UHL that all fetal tissue, irrespective of origin, must be managed in a respectful and dignified manner:
- 1.7.1** No fetal tissue will be disposed of as clinical waste unless specifically requested by the woman.
- 1.7.2** Fetal tissue will go to either the Mortuary or to Cellular Pathology (Histopathology). If considered appropriate, a small amount of fetal tissue may also be sent to Cytogenetics. *In exceptionally rare cases fetal tissue may be released to the women directly from the ward. This practise is not encouraged but is accommodated if, in the opinion of senior clinical staff, to do otherwise would cause significant further distress. This is only done if histological examination is not deemed necessary by clinical staff. A full record of this release must be recorded in the patients notes*

- 1.7.3 All fetal tissue will be handled with respect and disposed of with dignity as per the woman/families wishes.

2 POLICY SCOPE

- 2.1 This policy applies to *all* fetal tissue and products of conception up to 16 weeks gestation including samples where fetal tissue *may* be present subject to Section 3 below. See associated documents 10.2 for policies that apply to fetal tissue and products of conception over 16 weeks, namely Termination of Pregnancy in the Second and Third Trimester and Intrauterine Death in the Second Trimester and Stillbirth
- 2.2 This policy applies to all areas of Trust premises that may encounter fetal tissue from early pregnancy loss. In reality this is likely to be the Gynaecology / Maternity Wards, Theatres (day case, gynaecology, central operating department and general theatres), the Emergency Department, Cellular Pathology Department (Histopathology), Cytogenetics Department and the Mortuary.
- 2.3 Fetal tissue may also be received to the areas detailed in 2.2 from external sources (e.g. following forensic examination of early products of conception), including GP's, local private hospitals, Loughborough Day Surgery Unit and the Police.
- 2.4 Where it is difficult to establish gestational age, flexibility in the application of this policy should be exercised within the parameters defined by statutory legislation and professional guidelines – see Reference documents detailed in section 8.1

3 DEFINITIONS AND ABBREVIATIONS

The term 'Products of Conception' covers any tissue sample that is derived from known or suspected pregnancy, prior to 16 weeks gestation. This includes tissue passed spontaneously, tissue derived by therapeutic means (medical or surgical termination of pregnancy), also salpingectomy for suspected ectopic pregnancy, and placental tissue where suspected or known fetal tissue is present.

4 ROLES AND RESPONSIBILITIES

- 4.1 **Medical Director** holds the Human Tissue Authority (HTA) Corporate Licence for the Trust and as such shall have executive lead for this Policy and shall bring to the attention of the Trust Board any relevant matters relating to this Policy.
- 4.2 **Nursing, Midwifery and Medical staff (all relevant areas)** are responsible for ensuring appropriate consent for examination and disposal is obtained including full explanation of the process, that the pregnancy loss form is completed accurately and clearly, the fetal tissue is labelled correctly and transferred sensitively and appropriately to the mortuary, histopathology or cytogenetics.
- 4.3 **Histology staff (part of Cellular Pathology)** are responsible for processing fetal tissue in accordance with the wishes of the patient, disposing by incineration of any remaining tissue following histology if this method of disposal has been chosen, releasing any tissue remaining after histology to the patient if that is their wish.

- 4.4 Cytogenetics staff** are responsible for processing fetal tissue and transferring any remaining tissue in the original container to cellular pathology for disposal.
- 4.5 Mortuary staff** are responsible for ensuring the dignified and secure storage of fetal tissue and appropriate release of tissue for final disposal. This will be either to UHL's contact funeral director for communal cremation, directly to the patient or a private funeral director for private own arrangements or incineration or to UHL's clinical waste contractor. Mortuary staff are also responsible for completing all relevant documentation of release and conducting regular audits of all fetal tissue held in the UHL mortuaries.
- 4.6 Bereavement Services staff** are the point of contact for patients wishing to make their own arrangements and are responsible for arranging a suitable date and time for collection in liaison with the cellular pathology laboratory and mortuary. They may also assist histology and mortuary staff with the return of tissue to patients.
- 4.7 Histopathology (part of Cellular Pathology) Laboratory Manager** is responsible for maintaining an ongoing archive of the outcome of all fetal tissue. He/she is also responsible for ensuring that staff follow this policy.
- 4.8 Gynaecology Matron** is responsible for managing any errors in the paperwork and specimen identification throughout this process. This may be done in liaison with staff from the relevant area.
- 4.9 Head of Chaplaincy and Bereavement Services** are responsible for arranging for a chaplain to conduct the communal cremation service and sign the cremation record.
- 4.10 Head of Midwifery and Head of Service for Cellular Pathology** are responsible for ensuring compliance with this policy.

5 IMPLEMENTING AND DELIVERING THE POLICY

5.1 Patient welfare

- 5.1.1** Patients who have experienced fetal loss, irrespective of the method of loss, will be treated with sensitivity and respect at all stages of the processes outlined in this policy.
- 5.1.2** There are different religious, cultural, traditional and customary practices dealing with burials and cremations. Fetal remains are therefore to be handled with respect and due dignity throughout all stages of the process of examination and disposal. The communal cremation process has been established to respect the beliefs and practices of all the different members of the community.
- 5.1.3** Where parents express concern over communal cremation due to strictly cultural or religious practices and beliefs they will be offered help in discussing individual burial or cremation. Bereavement Services should be contacted for assistance.
- 5.1.4** Patients who have experienced fetal loss may not wish to be involved in decision making or know about the processes for examination and/or disposal. Staff will recognise and respect this choice and ensure that is recorded on the consent/pregnancy loss form accordingly.

5.2 Patient information

5.2.1 A specific Trust Information leaflet is available to help staff explain and patients understand the various options with regard to consenting for pathology tests and disposal of tissue afterwards. This is called “Pathological Examination and Sensitive Care of Tissue following Pregnancy Loss” – Information for Patients” and is available on

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjpy7f3xPf-AhWBQUEAHbr8AvqQFnoECBEQAQ&url=https%3A%2F%2Fyourhealth.leicestershospitals.nhs.uk%2Flibrary%2Fcsi%2Fpathology%2F777-pathological-examination-and-sensitive-care-of-tissue-after-pregnancy-loss%2Ffile&usq=AOvVaw0McrEGQL_GGkKGAqPKfFdy

5.2.3 A woman or couple may decide to make their own arrangements for disposal, either at own or in a local cemetery / crematorium using a funeral director or faith equivalent. Procedures are in place to support this choice. Staff should contact Bereavement Services to discuss details and obtain a copy of the specific fact sheet available for those who opt for own arrangement. This is called “Burial outside a Cemetery after early pregnancy loss – Information for Patients” and is available on

<https://yourhealth.leicestershospitals.nhs.uk/library/csi/pathology/778-burial-outside-a-cemetery-after-early-pregnancy-loss/file>

5.3 Consent

5.3.1 The medical and / or nursing staff responsible for the care of the patient will be responsible for determining the patient’s wishes in regard to consent for pathology tests and disposal of any fetal tissue or unapparent fetal tissue which might subsequently be found in products of conception or ectopic pregnancy.

5.3.2 Patients will be asked to sign a combined consent and pregnancy loss form for examination of fetal tissue by the histology lab (part of Cellular Pathology) and/or cytogenetic investigation (microarray investigation) if appropriate and for the disposal of fetal tissue. Forms are available in relevant areas across the Trust, only these forms should be used to take consent and record wishes regards disposal as they contain the necessary carbonated copies – these forms are given for information only in Appendix 2 and 3. (see Trust policy “Consent to Examination or Treatment” A16/2002)

5.3.3 Clinical staff should take care to advise families correctly about the time any tests may take in order to prevent unnecessary distress with regard to unachievable cremation dates or non-availability of the tissue for their own arrangements. Information about this is given in the consent form (see Appendix 2) and in the patient information leaflet on Sensitive Disposal.

5.3.4 If there is the possibility that pregnancy tissue may be needed for a medico-legal investigation, women must be advised of the usefulness for histology in terms of preserving DNA for genetic testing. The possible legal requirements for the tissue must be communicated to the histology lab and/or mortuary via the histology request form and pregnancy loss form.

5.3.5 UHL will only accept pregnancy loss specimens from external, non-UHL sources if the UHL consent and pregnancy loss forms are completed and accompany each specimen. Pregnancy loss specimens from external sources without consent for disposal will not be authorised for communal cremation by UHL staff as per the procedure detailed in 5.10.6. Any errors or omissions with regard to consent for histology and/or disposal will be referred back to the external source for rectifying. If the completed forms are not received by UHL, the specimens will also be returned.

5.3.6 If there are any issues with obtaining consent clinical/ward staff should refer to the UHL Policy for the Consent to Examination or Treatment (A16/2002)

5.4 Documentation

5.4.1 The following documentation must be completed in all cases:

Combined Consent and Pregnancy Loss form for examination by pathology and/or disposal of fetal tissue.

5.4.2 Combined Consent and Pregnancy Loss form will be a 4 part carbon-copy form:

- **Top copy (white):** given to the woman if they have requested to make their own burial or cremation arrangements – a separate Hospital / Private Non-viable Fetal Burial Form does NOT need to be completed. Otherwise, to be retained in the medical notes.
- **Second copy (yellow):** dedicated form only to be sent, with the fetal tissue, to the Cellular Pathology Department if histological examination is required or the mortuary for disposal only
- **Third copy (pink):** sent to Bereavement Services if the woman requests to make their Own burial or cremation arrangements
- **Bottom copy (blue):** retained in the case notes

5.4.4 The cytogenetics referral form must also be completed if a cytogenetic investigation is required and consented to; these forms are available from the laboratory.

5.4.5 A histology request form must also be completed and sent with the specimen to the histology lab if this test is required and has been consented to.

5.4.6 The combined Consent & Pregnancy Loss Form and cremation records will be stored securely and retained for a minimum of 25 years in accordance with correct storage of maternity records.

5.5 Confidentiality

5.5.1 All staff will respect patient confidentiality in accordance with normal hospital practice.

5.5.2 Fetal specimens for disposal only (i.e. where histological or cytogenetic examination is not required and/or not consented to) should be labelled with patient's S number or NHS number and date of loss ONLY. This ensures confidentiality is not breached at any stage. Full patient details must be provided on the Pregnancy Loss Form to enable the specimen to be registered on the mortuary patient database.

5.6 Transfer of fetal remains

5.6.1 Transportation of fetal tissues between clinical units/work areas will be undertaken sensitively and discreetly, mindful of the fact that the tissues may be emotionally provoking for some patients. Fetal tissue samples should never be transported on a patient's lap between theatre and the ward.

5.6.2 Fetal remains will be transferred by a porter to the histology lab (part of the cellular pathology department), cytogenetics department or the mortuary. Appropriate documentation, securely attached, will accompany fetal tissue at all times – see section 5.7.1 for more detailed information.

5.6.3 Fetal tissue sent to histology or cytogenetics must not be placed in the same bag as other specimens.

5.6.4 Traceability records detailing the collection, transport and receipt of specimens from the ward to the pathology laboratory or mortuary are kept on the ward – see Appendix 8 for details of minimum information required.

5.7 Process for handling and disposing of fetal tissue

5.7.1 Ward / Clinical Area procedures

- Following early pregnancy loss prior to 16 weeks gestation patients will be made aware of the Trust's policy and practice with regard to any tissue specimens – see section 5.2
- Patients will be required to sign a combined consent and pregnancy loss form for examination by pathology and disposal of fetal tissue – see sections 5.3 and 5.4
- Fetal tissue will be packaged appropriately and transported in sealed opaque containers to the appropriate department depending on the consent given and the pathology test required. This is described below and summarised in the flow chart on page 4
- **Consent given for and histological examination required** – the specimen will be fixed in formalin and placed in a watertight, sealable specimen container labelled with full patient details. The specimen should be sent to the Cellular Pathology Department (histology lab) with a completed histology request form, and a combined consent and pregnancy loss form – see section 5.8 for more details.

- **Consent given for and cytogenetic investigation required** – specimen will be placed in a sterile universal containing either sterile physiological saline or heparinised transport medium, labelled appropriately and transferred to the cytogenetics department. Samples must **not** be fixed in formalin. A separate small sample should be taken for cytogenetics – the entire evacuation products should **not** be sent. The specimen must be accompanied by a cytogenetics referral form, which includes consent – see section 5.9 for more details. It is not necessary to send a copy of the combined consent and pregnancy loss form to cytogenetics; any tissue remaining after cytogenetic testing will be sent to the histology lab for disposal according to the wishes of the women given on the form that accompanied the histology specimen.
- **Consent NOT given for OR pathology tests NOT required** – the specimen will be placed in an appropriate container with NO formalin or saline and labelled ONLY with the patients S number and date of loss. The specimen should be sent to the mortuary with a combined consent and pregnancy loss form labelled with full patient details.
- Before specimens and forms leave the ward they must be checked by an experienced nurse to ensure that they have been completed and the specimen(s) labelled correctly. Any problems should be rectified at this point before the specimen is sent to the necessary department.

5.8 Histological Investigations

- 5.8.1** The need for histology will be determined by the clinical team who must complete a histology specimen request form.
- 5.8.2** All fetal tissue and products of conception sent for histological investigation should be fixed in formalin in a watertight container prior to transport and labelled in accordance with Histopathology User Handbook (UHLSP-609-84) or the Histopathology website.
- 5.8.3** It is not histology laboratory practise to dissect any obvious fetus and/or fetal parts submitted in order to produce a histology report. If a more detailed examination of the fetus is medically advised or requested by the family the UHL Policy and consent form for Perinatal and Paediatric Post Mortem should be followed.
- 5.8.4** Ensure that the specimen container (**not the lid**) and request form contain full patient identification details. Wherever possible use addressograph labels. Essential information required:
- Full name
 - S number
 - Date of birth
 - Address
 - Consultant and ward for transmission of report.
 - Adequate clinical information and source
 - Destination for any copy reports
 - Required by' date for urgent specimens
 - **Printed** name of requesting clinician

- 5.8.5** The appropriate (yellow) copy of the combined Consent and Pregnancy Loss Form must also accompany the fetal tissue specimen to the histology lab (part of Cellular Pathology). This form should be sent in a discrete manner to maintain patient confidentiality, attached to the outside of the specimen container.
- 5.8.6** Any histology specimen received which is not correctly labelled or does not have the correct forms fully completed will be retained in the histology lab and details of the problem sent to the Gynaecological Sister/Matron for correction. A Datix incident report will be completed if there is a significant delay in histology processing as a result of incomplete/absent specimen paperwork or labelling.
- 5.8.7** Fetal loss specimens will be stored in a dedicated secure area in Cellular Pathology (histology lab).
- 5.8.8** Fetal tissue remaining after histological examination will normally be transferred to the mortuary for storage prior to disposal no sooner than 4 weeks after the histology report has been completed and approved. Exceptions to this timeline will only be available where urgent own arrangement has been requested for religious/cultural reasons.
- 5.8.9** At least once a week, specimens will be checked for any that have been authorised for more than 4 weeks. The combined consent /PLF form is scanned into the histology specimen computer record prior to the specimens being taken to the mortuary by histology lab staff. The histology POC Storage and Disposal Sheet is updated with the date of transfer of specimens to the mortuary.
- 5.8.10** If no tissue remains after histology and these specimens had been requested for own arrangement, an email will be sent to the mortuary and Bereavement Services in order that the family can be advised of this if they make contact to arrange collection of the tissue.
- 5.8.11** If own arrangement has been requested, the specimen will be suitably prepared and packaged for release to the family. The combined consent /PLF form will be updated and a tissue release form filled out detailing what material is to be given to the family. The specimen, combined consent /PLF form, tissue release form and an instruction sheet for the safe handling of formalin fixed tissue will be kept in the laboratory until Bereavement staff inform laboratory staff that the patient wishes to arrange collection. If the specimen is uncollected 12 weeks after the date of loss, histology staff will arrange for disposal by communal cremation – 5.12.2. All forms are scanned into the histology specimen computer record once the specimen has been released to either patient or mortuary
- 5.8.12** If sensitive incineration has been requested the tissue will be discarded into a **separate** yellow clinical waste container and a yellow clinical waste tie attached. The unique tie number will be recorded on the POC Storage and Disposal Record. The latter will be scanned into the histology LIMS and the original discarded. The sealed clinical waste container will be dispatched for incineration as per laboratory/Trust waste disposal policy using a **separate** consignment note

5.9 Cytogenetic investigations

- 5.9.1** The need for cytogenetic (microarray) investigation will be determined by the clinical team who must complete a cytogenetic request form. In the context of this policy this will primarily be from women who have had recurrent miscarriages.
- 5.9.2** Products of conception samples for cytogenetic analysis must contain chorionic villus material or fetal parts. A *separate* sample must be taken for cytogenetics – the entire evacuation products should ***not*** be sent.
- 5.9.3** All fetal tissue and products of conception sent for cytogenetic investigation must be placed in a sterile universal containing either sterile physiological saline or heparinised transport medium. The sample must be labelled in full but must as a minimum have two patient identifiers including the patient's full name and date of birth or NHS number in accordance with the requesting procedure information available on the Cytogenetics web pages in INsite.
- 5.9.4** Any cytogenetics sample received without a cytogenetics referral form will not be processed. The originating area will be contacted and the referral form requested. The referral form must be received by the laboratory within 2 working days or the sample will not be processed for microarray analysis and will be sent to the histology lab for disposal in accordance with the wishes of the woman.
- 5.9.5** The cytogenetics department will not accept any fetal tissue samples unless they are correctly identified. Unlabelled samples will be returned to the sender and an incident form completed.
- 5.9.6** When suitable samples have been obtained for DNA extraction and FISH, the original container and any remaining tissue will be transferred to the histology lab for disposal. Cytogenetics will inform histology by email that a specimen will be transferred to them for disposal.
- 5.9.7** Fetal loss specimens will be stored in a dedicated secure area in Cytogenetics.

5.10 Mortuary including disposal arrangements

- 5.10.1** The mortuary will receive and store fetal tissue in a dignified and secure area prior to collection by the Contracted Funeral Director or family for disposal.
- 5.10.2** If fetal tissue is received into the mortuary either incorrectly labelled/packaged or without the correctly completed forms clinical staff will be contacted and asked to assist in correcting the problems. Medical notes may also be requested so that a copy of the Pregnancy Loss Form may be taken.
- 5.10.3** If specimens have been sent to the mortuary instead of the histology lab in error, the specimen and any accompanying paperwork will be taken to the histology lab by mortuary staff.
- 5.10.4** Fetal tissue will be released from the mortuary to the Contracted Funeral Director or patients via Bereavement Services. Tissue should not be released from any other location.

- 5.10.5** Details of any specimens that have no consent for disposal should be sent to the Gynaecology Matron for investigation. Depending on the circumstances of the case further reasonable attempts to gain consent may be undertaken.
- 5.10.6** In cases where further contact is not appropriate or where consent is ultimately not obtained, the specimens will be sent for communal cremation. The documentation for this will be authorised by a member of staff at least as senior as the Deputy Clinical Director for the Women's and Children's Clinical Management Group – see appendix 5.
- 5.10.7** If sensitive incineration has been requested the tissue will be placed into a **separate** yellow clinical waste container and a yellow clinical waste tie attached. The unique tie number will be recorded in the Products of Conception Register and on the combined Consent/Pregnancy Loss form. The latter will be scanned into the mortuary patient database and the original discarded. The sealed clinical waste container will be dispatched for incineration as per mortuary/Trust waste disposal policy using a **separate** consignment note

5.11 Communal Cremation

- 5.11.1** UHL tissue will be collected on a regular basis by the Contracted Funeral Director from the Mortuaries, and placed in a coffin for cremation.
- 5.11.2** Fetal tissue will be cremated as part of a communal cremation at Gilroes Crematorium once a month, following a short broadly religious ceremony conducted by a member of the hospital Chaplaincy staff.
- 5.11.3** Families will not be invited to attend the communal cremation. Anyone who wishes to attend should be advised to consider a separate or private ceremony and contact Bereavement Services for advice.
- 5.11.4** Information leaflets made available to families include details about the recovery of ashes from individual remains cremated communally.

5.12 Own Arrangement

- 5.12.1** See section 5.8.11 for detailed instructions on the procedure for preparation and return of fetal tissue directly to families.
- 5.12.2** Where Own arrangements have been chosen but fetal tissue remains uncollected 12 weeks after the pregnancy loss date with no contact from the woman or couple, the Trust will not make further contact and will dispose of the tissue by communal cremation as per the original consent form.
- 5.12.3** If a private burial or cremation is planned, the top copy of the Pregnancy Loss Form should be given to the woman or their Funeral Director to give to the Cemeteries Authority. If for any reason a Pregnancy Loss cannot be completed a Non-Viable Fetal Burial Form must be completed instead.

5.13 Incineration

5.13.1 If a women specifically requests that her fetal remains are incinerated rather than cremated this will be organised in line with current HTA guidance i.e. the remains will be sent to UHL's clinical waste contractor, individually identified for separate incineration. A record of the unique incineration tag number will be recorded by the department dispatching the remains in order to identify the date of incineration if this is later requested.

5.14 Staff welfare

5.14.1 All staff involved in the management of each pregnancy loss will be made aware of this policy and receive mandatory training and instruction appropriate to their role. A record of this training will be kept by individual staff members and by trainers as per local department record keeping processes

5.14.2 Managers will ensure that staff are made aware that emotional and practical support is available either during or after their involvement in caring for a patient with a pregnancy loss.

5.14.3 Help and advice can be sought from staff by contacting -

Bereavement Services: bereavement.services@uhl-tr.nhs.uk	15194 and 15196 - LRI 13401 and 13417 - GH 14235 and 14236 – LGH
Head of Midwifery:	15476
Histology Lab (part of Cellular Pathology):	16593 or histopoc@uhl-tr.nhs.uk
Head of Service Cellular Pathology:	16595
Head of Service Cytogenetics:	15637
Gynaecology Matron:	15663 / 16262
Mortuary Manager:	16101
Head of Legal Services:	18585
Head of Bereavement Services	14243

5.15 Deviation from the policy

5.15.1 Any deviation from this policy should be reported using Risk Management (incident) forms. The relevant DATIX code (“fetal”) should be used so they can be easily identified in relation to this process

6 EDUCATION AND TRAINING REQUIREMENTS

- 6.1** The policy is available on the UHL Intranet under reference B3/2007.
- 6.2** Implementation and addressing any education and training requirements in the clinical area will be the responsibility of managers.

7 PROCESS FOR MONITORING COMPLIANCE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Completion of consent form is compliant with the Human Tissue Act. In particular there is no confusion regards the wishes of woman in terms of her involvement and choice in disposal of pregnancy remains	<ol style="list-style-type: none"> 1. Ward staff 2. Histology lab staff 3. Mortuary staff 	Check of every consent/ pregnancy loss form	<ol style="list-style-type: none"> 1. Before forms leave the ward 2. Before specimen is processed for histology and then disposed of 3. Before specimen is disposed of 	Non-compliant forms will be referred back to the consent taker promptly for clarification. Histology examination and/or disposal will not proceed until consent form is compliant.
Consent form for pathology examination and disposal was completed and filed in health record	Matron Gynaecology Services and Sexual health	Retrospective audit of 1% of health records of women who have had a pregnancy loss at less than 16weeks in UHL	Annually	Report to Gynaecology Services Governance Group for minuted discussion. Gynae Matron will be responsible for producing an action plan to address any issues. This action plan will be monitored by the GSGG
The Pregnancy Loss Form was completed and filed in health records	Matron Gynaecology Services and Sexual health	Retrospective audit of 1% of health records of women who have had a pregnancy loss at less than 16weeks in UHL	Annually	Report to Gynaecology Services Governance Group for minuted discussion. Gynae Matron will be responsible for producing an action plan to address any issues. This action plan will be monitored by the GSGG
The disposal process was correctly followed, including completion of all associated documentations	Cellular Pathology Deputy Service Manager	Retrospective audit of 3 months disposal records	Annually	Report to Cellular Pathology Quality and Risk Group. Cellular Pathology Deputy Service Manager will be responsible for producing an action plan to address any issues. This action plan will be monitored by the Cellular Pathology Quality and Risk Group
All staff involved in pregnancy loss have received training	Matron Gynaecology Services and Sexual health	Retrospective audit of training records	Annually	Report to Gynaecology Services Governance Group for minuted discussion. Gynae Matron will be responsible for producing an action plan to address any issues. This action plan will be monitored by the GSGG
No reported incidents of wrongful disposal including those reportable to the HTA (HTARIs)	HTA Designated Individual	Retrospective audit of incident reports – Datix and HTARI's	Annually	Report to HTA Governance Meeting. Appropriate service manager in area where incident occurred to provide assurance that preventative actions put in place as a result of the incident are effective.

8 EQUALITY IMPACT ASSESSMENT

If the policy will have any impact on equality, this should be described here. Otherwise the statement below should be inserted (see section 6.6 of the UHL Policy for Policies for more detail):

- 8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

9.1 References

- Royal College of Nursing (2007) *Sensitive disposal of all fetal remains: Guidance for nurses and midwives*. www.rcn.org.uk
- The Bristol Royal Infirmary Inquiry (2001) *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 – 1995*. www.bristol-inquiry.org.uk
- Human Tissue Authority (2006) *Human Tissue Authority: Code of Practice – the removal, storage and disposal of human organs and tissue*. www.hta.gov.uk
- HTA Newsletter issue 45 (May 2014) *Change to disposal code following reported of the inappropriate handling of fetal remains* www.hta.gov.uk
- Human Tissue Authority (March 2015) *Guidance on the disposal of pregnancy remains following pregnancy loss or termination*
https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf
- Institute of Cemetery & Crematorium Management (2008) *Foetal Remains Policy*. <http://www.iccm-uk.com/?pagenumber=27>
- Royal College of Obstetricians and Gynaecologists (2005) *Disposal following pregnancy loss before 24 weeks gestation*.
<https://www.rcoq.org.uk/guidance/browse-all-guidance/good-practice-papers/disposal-following-pregnancy-loss-before-24-weeks-of-gestation-good-practice-no-5/>
-

9.2 Related UHL documents

- Consent to examination or treatment – policy (Ref 16/2002)
- Patient Information Leaflet - Pathological examination and sensitive care (disposal) (Leaflet number 487)
- Patient Information Leaflet – Burial outside a cemetery following early pregnancy loss (Leaflet number 489)
- Histopathology user handbook, IN3752 (ID: 2U4SUVAQPZDY-475-81)
- Cytogenetics Laboratory Service web pages [Insite - Cytogenetics Laboratory Services \(xuhl-tr.nhs.uk\)](http://Insite - Cytogenetics Laboratory Services (xuhl-tr.nhs.uk))
- Retention of records policy (B10/2004)
- Policy for the Out of Hours Handling and Release of the Deceased (B12/2013)
- Information governance policy (B4/2004)
- Risk management strategy (A12/2002)
- Termination of pregnancy in the second and third trimester, Maternity procedure (UHL Guideline Register No: C30/2007)
- Intrauterine Death in the Second Trimester and Stillbirth, Maternity procedure (UHL Guideline Register No: C274/2016)
- Infection Prevention (B4/2005)
- Miscarriage- Management of Missed/delayed/Incomplete Miscarriage and Threatened Miscarriage (C30/2013)
- Investigation and Management of Pregnancy of Unknown Location and Tubal Ectopic Pregnancy (C17/2009)
- Cellular Pathology (histopathology and mortuary) procedures for the sensitive reception, accommodation and disposal of products of conception specimens (PR3841)
- Procedure for cremation of fetal remains (dated 11/4/16) Bereavement Services procedure
- Waste Management Policy (Ref – A15/2002)
- Policy for the Consent to Examination or Treatment (Ref - A16/2002)
- Taking a Deceased Child Home (where registerable death) - (B17/2022)

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 Review and monitoring (audit) process

10.1.1 This policy will be subject to evaluation, review, and audit across CMG's. This process will be co-ordinated by the Head of Midwifery.

10.1.2 Compliance with the process will be overseen by the matron in Women's, matron in theatres and laboratory manager in cellular pathology. If concerns cannot be resolved by those individuals, then they should be escalated to the Head of Service for Cellular Pathology, Head of Midwifery and Head of Nursing for Support Services Division.

10.1.3 The Head of Midwifery and Head of Service for Cellular Pathology are responsible for ensuring monitoring occurs.

10.2 Policy review process

10.2.1 This policy will be reviewed by a multidisciplinary group across all areas covered by the policy.

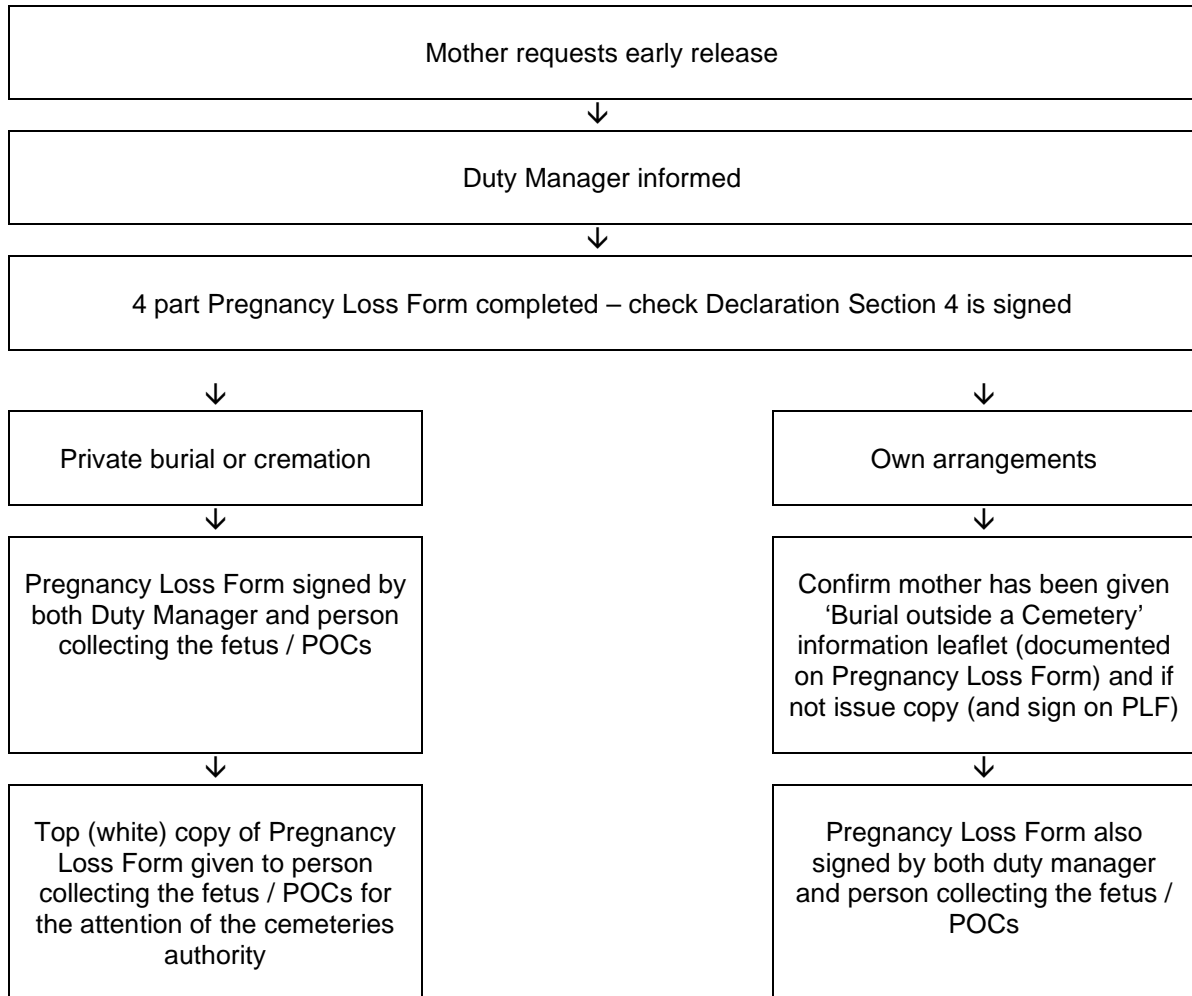
Appendix 1: Out of Hours release procedure

Release of fetal tissue during working hours Monday – Friday is preferable. Where a patient requests 'out of hours' release ensure she has a copy of the 'Information on Burial Outside a Cemetery' fact sheet (see next page) and:

At night: Discuss release with patient and inform that release during the next working day is preferable. If this is declined the on-call duty manager should be contacted.

Bank holiday: The on-call duty manager should be contacted.

The procedure for the on-call duty manager is:



NOTE:

Products of Conception only have the patient's ID number on the box;

AND

Are stored in separate fridges in the mortuary
CONTACT ON-CALL APT VIA UHL SWITCHBOARD FOR ADVISE ON LOCATION

Record release via Out of Hours Mortuary Register and leave the yellow copy of the signed Pregnancy Loss Form with the register.

Appendix 2: Combined Pregnancy Loss Consent and Disposal form

- Top (white) copy – patient if Own Arrangement is chosen or notes
- Third (pink) copy – bereavement services if Own Arrangement is chosen or notes
- Bottom (blue) copy - notes

*** FOR INFORMATION ONLY – DO NOT PRINT & USE ***

Consent Form for Examination and Sensitive Disposal of Fetal Tissue from Early Pregnancy Loss

Gynaecology & Emergency Department Staff Only


Patient ID Label or complete below:
Label/write details on all copy forms below

Unit No: _____

Name: _____

Address: _____

D.O.B: _____ Ward: _____



University Hospitals of Leicester NHS Trust

Ward:

Date of loss: / /

This includes all samples which may derive from pregnancy, generally before 16 weeks gestation, and includes salpingectomy or other operation for suspected ectopic pregnancy. Before completing this form please refer to Patient Information Leaflet on 'Pathological Examination and Sensitive Disposal'.

Please circle 'Y' or 'N' to indicate Yes or No in all the boxes below as appropriate. **DO NOT** mark in the other greyed out boxes. Use a ball point pen and keep within the boxes to ensure instructions transfer legibly to copies beneath.

Section A: PATHOLOGY EXAMINATION (Patient to complete)		
Q1 The purpose of the investigations have been explained to me by discussion and/or the patient information leaflet 'Pathological Examination and Sensitive Disposal'	Y	N
Q2 I consent to the tissue being examined should it be required, and if appropriate, chromosome analysis being undertaken	Y	N
Patient signature: _____ Print name: _____		
Section B: PART 1 SENSITIVE DISPOSAL (Patient to complete)		
I wish to make a decision regarding disposal of fetal tissue. If NO, sign below and go to SECTION D	Y	N
I confirm that I have been offered written and verbal information on the options available to me. However, I have declined this information and do not wish to be involved in making a decision about the method of disposal of my baby/pregnancy remains. I understand that the hospital will arrange for disposal by communal cremation.		
Patient signature: _____ Print name: _____		
Section B: PART 2 SENSITIVE DISPOSAL - PLEASE CHOOSE ONE OPTION ONLY (Patient to complete)		
Option A I choose hospital disposal by COMMUNAL CREMATION	Y	
Option B I choose to make my OWN ARRANGEMENTS. I will comply with the guidance given to me and note that if I have not collected the tissue within 3 months, I understand the hospital will make arrangements for disposal by communal cremation. I have taken a copy of this form to assist with making my own arrangements.	Y	
Option C Hospital disposal by INCINERATION	Y	
I have chosen to take a copy of this form	Y	N
Patient signature: _____ Print name: _____		
Section C: IF PATIENT HAS CHOSEN OWN ARRANGEMENTS FOR DISPOSAL (Clinical staff to complete)		
a) Information leaflet "Burial outside a cemetery after early pregnancy loss" given to patient	Y	
b) Give the patient the TOP copy of this form - they will need this to organise a private cremation or burial	Y	
c) Send the pink copy of this form to Bereavement Services	Y	
Staff signature: _____ Print name: _____		
Section D: DECLARATION (MUST be completed by Doctor, Registered Nurse, Midwife, Operating Department Practitioner)		
The following pathology investigations are clinically required:		
Histology: <input type="checkbox"/>	Cytogenetics: <input type="checkbox"/>	NONE (to mortuary for disposal): <input type="checkbox"/>
I confirm all samples are correctly labelled as per Section C of the pathology/mortuary form underneath	Y	
I declare that the above fetal remains have at no time shown signs of life and are less than 24 weeks gestation	Y	
I confirm that this form has been completed correctly by myself AND the patient	Y	
Nurse/Doctor/ODP Signature: _____ Print name: _____		
GMC/Profession No: _____ Date: _____		

Top copy (white) - to be given to the patient if requested / Own Arrangements is chosen or retained in notes

**Appendix 3: Combined Pregnancy Loss Consent and Disposal form
Second (Yellow) copy - for pathology examination or
mortuary disposal**

***** FOR INFORMATION ONLY – DO NOT PRINT & USE *****

Consent Form for Examination and Sensitive Disposal of Fetal Tissue from Early Pregnancy Loss

Pathology/Mortuary Copy


Patient ID Label or complete below.
Label/write details on all copy forms below

Unit No: _____

Name: _____

Address: _____

D.O.B: _____ Ward: _____



University Hospitals of Leicester
NHS Trust

Ward:

Date of loss: / /

This includes all samples which may derive from pregnancy, generally before 16 weeks gestation, and includes salpingectomy or other operation for suspected ectopic pregnancy. Before completing this form please refer to Patient Information Leaflet on 'Pathological Examination and Sensitive Disposal'.

*Please circle 'Y' or 'N' to indicate Yes or No in all the boxes below as appropriate, **DO NOT** mark in the other greyed out boxes. Use a ball point pen and keep within the boxes to ensure instructions transfer legibly to copies beneath.*

Section A: PATHOLOGY EXAMINATION (Patient to complete)		
Q1 The purpose of the investigations have been explained to me by discussion and/or the patient information leaflet 'Pathological Examination and Sensitive Disposal'	Y	N
Q2 I consent to the tissue being examined should it be required, and if appropriate, chromosome analysis being undertaken	Y	N
Patient signature: _____ Print name: _____		
Section B: PART 1 SENSITIVE DISPOSAL (Patient to complete)		
I wish to make a decision regarding disposal of fetal tissue. If NO, sign below and go to SECTION D	Y	N
<small>I confirm that I have been offered written and verbal information on the options available to me. However, I have declined this information and do not wish to be involved in making a decision about the method of disposal of my baby/pregnancy remains. I understand that the hospital will arrange for disposal by communal cremation.</small>		
Patient signature: _____ Print name: _____		
Section B: PART 2 SENSITIVE DISPOSAL - PLEASE CHOOSE ONE OPTION ONLY (Patient to complete)		
Option A I choose hospital disposal by COMMUNAL CREMATION	Y	
Option B I choose to make my OWN ARRANGEMENTS. I will comply with the guidance given to me and note that if I have not collected the tissue within 3 months, I understand the hospital will make arrangements for disposal by communal cremation. I have taken a copy of this form to assist with making my own arrangements.	Y	
Option C Hospital disposal by INCINERATION	Y	
I have chosen to take a copy of this form	Y	N
Patient signature: _____ Print name: _____		
Section C: INFORMATION ONLY - PATHOLOGY/MORTUARY STAFF can ignore circles in the right hand columns		
This form <u>MUST</u> accompany the loss to either the laboratory or the mortuary, instructions are below:		
HISTOLOGY: Send this form AND a 'Histology Specimen Request' form with the sample to the lab. Sample to be labelled with full patient details.		
CYTOGENETICS: Send a separate sample and a 'Cytogenetics Specimen Request' form to cytogenetics. Any tissue remaining after testing will be transferred to histology for disposal. Sample to be labelled with full patient details.		
MORTUARY: If pathology is NOT required, send this form and ALL the sample to the mortuary for disposal ONLY . Sample to be labelled with full patient details.		
Section D: DECLARATION (MUST be completed by Doctor, Registered Nurse, Midwife, Operating Department Practitioner)		
The following pathology investigations are clinically required:		
Histology: <input type="checkbox"/>	Cytogenetics: <input type="checkbox"/>	NONE (to mortuary for disposal): <input type="checkbox"/>
I confirm all samples are correctly labelled as per Section C of the pathology/mortuary form underneath		
I declare that the above fetal remains have at no time shown signs of life and are less than 24 weeks gestation		
I confirm that this form has been completed correctly by myself AND the patient		
Nurse/Doctor/ODP Signature: _____	Print name: _____	
GMC/Profession No: _____	Date: _____	

Second copy (yellow) - send to **histology or mortuary** as required

Appendix 4: Hospital / Private Non-viable Fetal Burial Form

***** FOR INFORMATION ONLY – DO NOT PRINT & USE *****

Only to be used if a Pregnancy Loss form cannot be / has not been completed.

University Hospitals of Leicester **NHS**
NHS Trust

Hospital / Private Non-viable Fetal Burial Form

THIS FORM IS TO BE COMPLETED FOR THE BURIAL OR CREMATION OF A FETUS OF LESS THAN 24 WEEKS GESTATION IN WHICH THERE WERE NO SIGNS OF LIFE

SECTION 1 (Must be completed by Registered Midwife or Doctor)

This is to certify that

Of

Was delivered of a fetus of less than 24 weeks gestation in which there were no signs of life, on:

Date

Site of delivery LGH LRI

Ward Gestation weeks

Signature Print name Date

Designation Midwife Doctor

SECTION 2 (To be completed by the person receiving the fetus)

I have received the fetus of

And I understand my responsibilities to dispose of it in a manner which does not cause offence to any member of the public.

Relationship to fetus: Funeral Director / Other (state)

Signature Print name

Contact Number Date

Witnessed by Print name Date

Designation Anatomical Pathology Technician Duty Manager

SECTION 3 (To be completed by the cemeteries / crematorium department)

I confirm the arrangements have been made to bury the above named fetus in:

Signature Print name Date

Designation

Ward staff

Forward form to Bereavement Services with Pregnancy Loss Form (under 16 completed weeks gestation) or Infant Bereavement Notification (over 16 completed weeks gestation)

Bereavement Services

Form to be returned to UHL Bereavement Services on completion; Leicester Royal Infirmary, Leicester LE1 5WW

Appendix 5: Mortuary Products of Conception Register

***** FOR INFORMATION ONLY – DO NOT PRINT & USE *****

PRODUCTS OF CONCEPTION	University Hospitals of Leicester  <small>NHS Trust</small>
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Date in Mortuary	S-Number	✓ Private Disposal	✓ Communal Cremation	✓ Errors tray LRI	Received by	Comment

RELEASE FOR COMMUNAL CREMATION

From: LRI GGH LGH Date of release: Released by: Released to: Tag Number:

COMMUNAL CREMATION

Funeral Representative: UHL Representative: Date of Cremation:

White Copy to remain in book, Blue copy to accompany POC's for communal cremation & to be returned to LRI Mortuary upon completion

NB: Paper copies of this document may not be most recent version. The definitive version is held in the Policy and Guidelines Library.

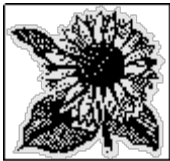
Appendix 6: Fetal cremation ceremony

Introduction

In this ceremony we come
to mark the loss of these little ones
and to commit their remains to be cremated.

For some, these little ones
represent painful and distressing circumstances,
and there is a desire to forget and move on.

For others, they represent
a much wanted baby and a tragic and painful loss.
Whatever the circumstances,
this ceremony is a mark of respect
for the potential of life that has not been realised.



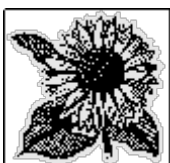
Silent Reflection

We pause to remember
the grief and sadness
at the passing of these little ones:
The intense pain of loss,
the feelings of emptiness,
the unanswered questions,
the shattering of hopes,
the confusion and despair.

Silence

Prayer

Loving God,
we pray for all those
affected by the loss of these little ones.
Help, comfort and support them.
Do not let their grief overwhelm them.
Give them strength for each day,
to weep when they should weep
and to face the future with courage.
Fill their emptiness with hope
and heal the pain of parting.
Amen.



Prayer of Commendation

God of all mercies, ever-loving, giver of all comforts:
We now entrust these little ones
into your safekeeping for ever.
In your great mercy,
enfold them into your loving presence
and surround them with your never-failing care.
Amen.

Committal

At this point the curtain is closed as the following words are said:

We now commit these remains
to be cremated.
Fleetingly known,
yet often remembered.
Safe from all harm,
Rest in Peace.

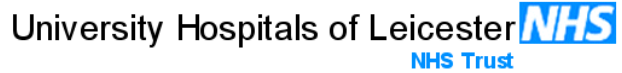


Blessing

Now let us go from this place with hope,
carrying with us the strength of the source of all life.
May the peace of God be with us
now and always.
Amen.

*These prayers and readings are adapted from various sources.
Details can be obtained from the Chaplaincy.*

Appendix 7: Trust Authorised Communal Cremation Form/Letter



Leicester Royal Infirmary
Leicester
LE1 5WW
Tel: 0330 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

To: Mortuary Manager, LRI
From: Gynaecology Assessment Unit (GAU)

Please find enclosed _____ specimen container(s) with products of conception from GAU, LRI. These products do not have the necessary completed paperwork and we have been unable to contact the patient(s) to gain consent. It is now 12 weeks following the actual pregnancy loss and I am therefore requesting on behalf of the Gynaecology service and Womens and Childrens CMG that these products of conception are disposed of in compliance with the UHL Policy for Disposal of Fetal Remains (under 16weeks).

Patient S Number	Date of Loss

Regards

Member of staff at least Deputy Clinical Director for the Women's and Children's Clinical Management Group

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester, LE1 5WW
Website: www.uhl-tr.nhs.uk
Chairman Karamjit Singh **Chief Executive** Mr John Adler

Appendix 8: Example of Fetal Remains Traceability Log ***** FOR INFORMATION ONLY – DO NOT PRINT & USE *****

Fetal Remains Specimen Traceability Log	Ward / Department
--	--------------------------

Record individual specimens for the same patient on a separate line

Once specimens have been received by the laboratory/mortuary this form must be returned to the original ward/department for filing

DATE SPECIMEN COLLECTED	S NUMBER - please print clearly	CONTAINER USED & No. Histology pot White pot Large white Universal	DESTINATION Histology lab Mortuary Cytogenetics Home from ward	SPECIMENS TO COLLECTION POINT/SLUICE Staff member (print surname) date & time	SPECIMENS COLLECTED BY Porter (print surname) date & time	SPECIMENS RECEIVED BY Staff member (print surname) date & time

NB: Paper copies of this document may not be most recent version. The definitive version is held in the Policy and Guidelines Library.