

Title: NHS GG&C Policy on the Handling and Disposal of Fetal Tissue (up to and including 23+6 weeks gestation)

Objectives: This document is to provide guidance on the handling and disposal of tissue which contains, or potentially contains, fetal tissue of up to and including 23+6 weeks gestation.

Scope: All pregnancy tissue up to and including 23+6 weeks gestation

Audience: This guideline is intended for use by healthcare professionals working within GGC. In particular this is relevant to Pathology Department Medical and BMS Staff, Mortuary MTO Staff Obstetrics and Gynaecology, Medical, Nursing, Midwifery and theatre staff in Obstetrics and Gynaecology, Medical and Nursing Staff working in Accident and Emergency

Body of Guideline:

Aims and Scope

This document is to provide guidance on the handling and disposal of tissue which contains, or potentially contains, fetal tissue of up to and including 23+6 weeks gestation.

This includes:

- Medical Termination of Pregnancy tissue
- Surgical Termination of Pregnancy tissue
- Ectopic Pregnancy tissue
- Any tissue from an Early Pregnancy Loss (including spontaneous loss, medically managed, surgically managed and MVA)
- Fetuses of up to and including 23+6 weeks gestation where there has been a Post Mortem Examination
- Retained products of conception specimens

Our aim is to ensure that all fetal tissue is handled appropriately and disposed of respectfully. This has been defined as Shared Cremation with agreement of the Department of Obstetrics and Gynaecology. The purpose of this document is to provide guidance and clarity as to the appropriate examination of tissue and the paperwork which is required to allow this examination and disposal.

Specimen Flow

Medical Termination of Pregnancy

The majority of these specimens do not require histopathological assessment. If no histopathological examination is required then the tissue should be transferred directly to the Mortuary for sensitive

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disposal (cremation) along with a completed copy of Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2).

If the tissue is to be released directly to the family then a release of pregnancy tissue form should be completed by clinical staff. If the patient opts to take the specimen from the Pathology Department then the relevant section of Form 2 should be completed and submitted with the specimen. In addition, a completed PATH-COM-COMF-006 form accepting the associated risks of taking formalin fixed tissue from the pathology department requires to be completed. Pathology staff will complete this form with the family collecting the tissue.

If there are concerns about fetal anomalies and examination is required then appropriate Post Mortem Consent should be obtained.

Any specimen received without appropriate documentation will be stored in the Pathology Department and logged as a non-conformance. The specimen will not be processed until the correct paperwork is received and may be returned to the sender. If the correct paperwork has not been received within 12 weeks, the specimen will be sampled and processed to FFPE blocks and stored in the pathology archives. No glass slides or formal histopathology report will be prepared until a completed copy of Form 2 is received by the pathology department. Following receipt of a completed copy of Form 2, a replacement request form will be required in order to generate a report on Trak Care. The remainder of the specimen will be sensitively disposed of without further examination.

NB: If a molar pregnancy is suspected clinically, accurate details of the clinical team treating the patient must be included with the request form so that if an error is identified in Form 2, the clinical team can be contacted regarding the non-conformance in a timely manner.

A Datix will be raised by Pathology if an error is made in a Form 2 that is not rectified within 4 weeks of submitting the specimen. If a Form 2 is being resubmitted, then a replacement pathology request must be made via Trak Care to generate a pathology report on Trak Care.

Surgical Termination of Pregnancy

These specimens do not require histopathological assessment. They should be transferred directly to the Mortuary for sensitive disposal (cremation) along with a completed copy of Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2). If the patient opts to take the specimen from the Pathology Department then the appropriate section of Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2) should be completed and submitted with the specimen. In addition, a completed PATH-COM-COMF-006 form accepting the associated risks of taking formalin fixed tissue from the pathology department requires to be completed. Pathology staff will complete this form with the family collecting the tissue.

Any specimen received without appropriate documentation will be stored in the Pathology Department and logged as a non-conformance. The specimen will not be processed until the correct

paperwork is received and may be returned to the sender. If the correct paperwork has not been received within 12 weeks, the specimen will be sensitively disposed of without further examination.

Ectopic Pregnancy Tissue

These specimens should be sent for histopathological examination for confirmation of ectopic pregnancy and assessment of associated pathology. These specimens should be submitted to the Pathology Department with a Pathology Request form (containing relevant clinical information) and with a completed Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2). Following reporting, any residual tissue will be transferred from the Pathology Department to the Mortuary for sensitive disposal (cremation). If the patient opts to take the specimen from the Pathology Department then the appropriate section of Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2) should be completed and submitted with the specimen. In addition, a completed PATH-COM-COMF-006 form accepting the associated risks of taking formalin fixed tissue from the pathology department requires to be completed. Pathology staff will complete this form with the family collecting the tissue.

Any specimen received without appropriate documentation will be stored in the Pathology Department and logged as a non-conformance. The specimen will not be processed until the correct paperwork is received and may be returned to the sender. If the correct paperwork has not been received within 12 weeks, the specimen will be placed into FFPE blocks and processed for histology. The FFPE blocks to confirm the presence of an ectopic pregnancy will remain in the pathology archives and a histopathology report will be generated when a completed copy of Form 2 is received. If this is required, a replacement specimen request form will be required to generate a report on Trak Care.

Early Pregnancy Loss Tissue

This includes spontaneously passed tissue and surgically removed tissue. It is for the sender to decide whether histopathological examination is desirable.

Possible reasons for examination include

- Confirmation of products of conception
- Exclusion of gestational trophoblastic disease
- Attempts at determining cause of recurrent miscarriage

If histopathological examination is required, then the specimen should be submitted to the Pathology Department with a Pathology Request form (containing relevant clinical information) and a completed Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2). Following reporting, any residual tissue will be transferred from the Pathology Department to the Mortuary for sensitive disposal (cremation). If the patient opts to take the specimen from the Pathology Department then the relevant section of Authorisation for burial or cremation following pregnancy loss up to 23 weeks and 6 days gestation (Form 2) should be completed and a completed PATH-COM-COMF-006 form accepting the associated risks of taking

formalin fixed tissue from the pathology department requires to be completed. Pathology staff will complete this form with the family collecting the tissue.

If no histopathological examination is required and the patient opts for the hospital to sensitively dispose of the specimen, then the specimen should be transferred directly to the Mortuary for sensitive disposal (cremation) along with a completed Form 2. If no histopathological examination is required and the patient opts to take the tissue from the hospital the relevant section of Form 2 should also be completed to provide an audit trail for the fetal tissue as well as a completed release of pregnancy tissue form. The tissue can be passed to the patient in a suitable container. The paperwork (Form 2) should be sent to the Mortuary for registration.

Any specimen received without appropriate documentation will be stored in the Pathology Department and logged as a non-conformance. The specimen will not be processed until the correct paperwork is received and may be returned to the sender. If the correct paperwork has not been received within 12 weeks, the specimen will be sampled to FFPE block but no glass slide or formal histopathology report will be available until a completed Form 2 is received. The remainder of the specimen will be sensitively disposed of without further examination. If a histopathology report is required following receipt of the completed form 2, then a replacement pathology request will be required to generate a report on Trak Care.

NB: If a molar pregnancy is suspected clinically, accurate details of the clinical team treating the patient must be included with the request form so that if an error is identified in Form 2, the clinical team can be contacted regarding the non-conformance in a timely manner. A Datix will be raised by Pathology if an error is made in a Form 2 that is not rectified within 4 weeks of submitting the specimen. If a Form 2 is being resubmitted, then a replacement pathology request must be made via Trak Care to generate a pathology report on Trak Care.

Recurrent Miscarriage or Suspected Underlying Cytogenetic Cause of Pregnancy Loss

RCOG Guidelines (GT17) recommend that cytogenetic analysis of the products of conception should be performed for all couples with a history of recurrent miscarriage, (loss of three or more pregnancies).

Previously this required division of tissue for both histological and cytogenetic analysis. With the centralization of laboratory services this is no longer necessary. Products of conception should be sent complete to Cytogenetics (in a dry sterile container – not in formalin) with the relevant request form giving a clear history and a completed Form 2. Please ensure that the sample container itself is also labelled with appropriate patient identifiers. Following examination within both Cytogenetics and Pathology, any residual tissue will be transferred from the Pathology Department to the Mortuary for sensitive disposal (cremation). The same applies to the examination of fetal and placental tissues where an underlying cytogenetic cause is suspected e.g. following detection of abnormality on early ultrasound scan or miscarriage associated with raised risk of aneuploidy on antenatal screening.

Fetuses up to and including 23+6 weeks gestation where there is to be a Post Mortem Examination

These specimens should be transferred directly to the mortuary along with any associated placental tissue and appropriately completed Post Mortem Consent Forms. The further handling of these requests is detailed elsewhere.

Retained Products of Conception Specimens in which there has been a separately identified fetus

This clinical scenario has been previously discussed at the Sensitive Disposal Committee. It has been agreed that there is no requirement to supply a Form 2. Surplus tissue will be disposed of as clinical waste.

Tissue Type	Tissue Flow	Sample and Paperwork Required
Medical Termination of Pregnancy tissue	Histopathology assessment not required and tissue for shared cremation/sensitive disposal	-pathology/tissue specimen dry specimen -completed Form 2 Send to the mortuary, QEUEH
Medical Termination of Pregnancy tissue	If specimen does not require Histopathology assessment and being released to family without further assessment	-pathology/tissue specimen dry -completed Form 2 – send to pathology for registration -release of pregnancy tissue form -Tissue to be sent with parent
Medical Termination of Pregnancy tissue	If specimen requires histopathology assessment	-pathology/tissue specimen in formalin -completed Form 2 -pathology request form Send to the pathology department, QEUEH *
Medical Termination of Pregnancy tissue	If specimen requires cytogenetic and histopathology assessment	-pathology/tissue specimen in sterile dry pot -completed Form 2 -pathology request form - cytogenetics request form Send to the Cytogenetics department, QEUEH*
Medical Termination of Pregnancy tissue	If specimen requires post-mortem assessment	-pathology/tissue/fetal specimen -completed Form 2 -pathology request form (for placenta)

		<p>-completed PM authorisation form</p> <p>Send fetus and placenta as dry sample to mortuary</p> <p>Send to the pathology department, QEUH*</p>
Surgical Termination of Pregnancy tissue	Histopathology assessment not required	<p>-pathology/tissue specimen dry specimen</p> <p>-completed Form 2</p> <p>Send to the mortuary, QEUH*</p>
Surgical Termination of Pregnancy tissue	If specimen requires histopathology assessment	<p>-pathology/tissue specimen in formalin</p> <p>-completed Form 2</p> <p>-pathology request form</p> <p>Send to the pathology department, QEUH*</p> <p><i>If suspected molar pregnancy please ensure clear documentation of lead clinician and contact details</i></p>
Surgical Termination of Pregnancy tissue	If specimen requires cytogenetic and histopathology assessment	<p>-pathology/tissue specimen in in dry sterile pot</p> <p>-completed Form 2</p> <p>-pathology request form</p> <p>-cytogenetic request form</p> <p>Send to the Cytogenetics department, QEUH*</p>
Ectopic Pregnancy tissue	Histopathology required	<p>-pathology specimen in formalin</p> <p>-completed Form 2</p> <p>-pathology request form</p> <p>Send to Pathology Department, QEUH*</p>
Tissue from an Early Pregnancy Loss (pregnancy loss up to 11+6 weeks gestation)	Histopathology required	<p>-pathology/tissue specimen in formalin</p> <p>-completed Form 2</p> <p>-pathology request form</p>

		Send to Pathology Department, QEUH *
Tissue from an Early Pregnancy Loss (pregnancy loss up to 11+6 weeks gestation)	Histopathology NOT required	-pathology specimen (dry) -completed Form 2 Send to the Mortuary, QEUH
Tissue after recurrent miscarriage (3 consecutive early losses)	Tissue for histopathology and cytogenetics	-pathology specimen in dry sterile container -pathology request -cytogenetics request -completed form 2 Send to Cytogenetics department QEUH*
Fetus of between 11 and 23+6 weeks gestation where there is a Post Mortem Examination (postmortem requests for less than 11 weeks gestation MUST be discussed with a pathologist)	Histopathology and Post Mortem Examination required	-pathology/tissue/fetal specimen -completed Form 2 -pathology request form (for placenta) -completed PM authorisation form Send fetus and placenta as dry sample to mortuary Send to the mortuary department, QEUH*
Retained products of conception (RPOC) specimen in which there has been a separately identified fetus.	Histopathology required	-Pathology/tissue specimen in formalin -Pathology request to confirm RPOC -No need for Form 2 for RPOC component Send to Pathology Department QEUH*
Retained products of conception (RPOC) specimen with NO separately identified fetus	Histopathology required	-Pathology/tissue specimen in formalin -Pathology request to confirm RPOC -Completed Form 2 Send to Pathology department QEUH*

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*if parents want to take tissue home from mortuary following cytogenetics and histopathology, they will require to have a -Form PATH-COM-COMF-006 completed at the time of collection from pathology. This form makes them aware of the risks of handling tissue that has been stored in formalin. Pathology staff will complete the form with the family collecting the tissue. Photographic Identification is required for collection of tissue. Please make the family aware that there may not be any tissue remaining after examination.

Author: Dr Sylvia Wright, Consultant Pathologist, QEUEH, Glasgow,

Co-Author: Dr Claire Higgins, Consultant O&G, QEUEH, Glasgow, Dr Felicity Watson, Speciality Trainee, O&G, QEUEH, Glasgow

Authorised by Dr Ros Jamieson, Clinical Director Gynaecology

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