

INDEPENDENT REVIEW GROUP ON

RETENTION OF ORGANS AT POST-MORTEM

Report on Phase 3

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Phase 3 report of the Independent Review Group on the
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Phase 3 report of the Independent Review Group on the
Retention of Organs at Post-Mortem

A copy of the main documents received by the Review Group during the course of its work, including transcripts of oral sessions, can be viewed on the Review Group's website at www.show.scot.nhs.uk/scotorgrev.

A copy of the material is also available for public viewing at the Scottish Executive Library, located at Saughton House, Broomhouse Drive, Edinburgh. Those wishing to consult this material should telephone 0131-244 4552 to arrange an appointment. A list of the material, and a copy of it, can also be made available on request from the Scottish Executive Health Department, G(ER), St Andrew's House (telephone 0131-244 3194).

SUMMARY OF RECOMMENDATIONS

FAMILIES' ATTITUDES AND EXPERIENCE

- 1 Trusts' arrangements for dealing with enquiries about organs retained under past post-mortem examination practice (i.e. before the end of 2000) must remain in place until the end of the formal 5-year period, i.e. until 17 October 2007 (paragraph 44).

AUTHORISATION FORMS

- 2 The authorisation forms as drafted contain a single question including research with medical education, training and audit. Any consultation on our report should specifically ask for views on whether families should be able to consider as a separate issue the question of authorising the research use of tissue blocks and slides or organs retained at post-mortem examination (paragraph 64) basis.
- 3 In respect of a hospital post-mortem examination on a child, the Review Group takes the view that it would be reasonable to proceed the examination where only one parent was present to give authorisation, provided that when authorisation is being sought, enquiries are made as to whether the absent parent would be likely to object. If it appeared likely that there would be disagreement then ordinarily the post-mortem examination would not take place until further enquiries were made of the absent parent or legal advice taken. Where both parents with authority to agree a post-mortem examination are in dispute with each other then the examination should not go ahead. Given the sensitivities about these issues, we would wish to see wider views canvassed on the suggested approach (paragraph 72).
- 4 Where a local authority has guardianship of a child, it should not authorise a post-mortem examination without consulting the parents. If the parents objected, the examination would not normally go ahead (paragraph 84).
- 5 In the case of adults, the authorisation form would allow hospital staff to discuss the possibility of the deceased's nominated representative or nearest relative granting permission over the telephone for another person to give authorisation. The form recognises, however, that this would only be done in exceptional circumstances and that any such discussion would have to be witnessed by another member of staff. This approach needs to be the subject of wider consultation (paragraph 76).

- 6 All hospital staff who will be involved in seeking authorisation must be properly trained, and the authorisation forms should act as a focal point for that training. The Chief Medical Officer should explore this with the Deans of Medical Schools, Medical Directors, the Royal Colleges and NHS Education for Scotland. Such training initiatives should also take account of others being developed elsewhere in the UK (paragraphs 79 and 150). Implementation of these training initiatives should be speeded up (paragraph 130).
- 7 There also needs to be greater public awareness of the hospital post-mortem examination process. The Executive should explore the possibility of developing an equivalent of the Teaching Resource Pack which has been produced for organ donation and transplantation. A further possibility might be the establishment of an education programme with the participation of the Royal College of Pathologists (paragraph 80).
- 8 The authorisation forms do not include a section allowing specific authorisation of genetic testing, on the grounds that *any* post-mortem examination has the potential to reveal diseases or conditions with implications for the family, and this would be masked if genetic conditions were to be singled out. Nonetheless, we recognise that genetic information can be different and would wish to see wider discussion of this point before the forms are finalised (paragraph 81).
- 9 So that the wishes of the deceased can be prioritised, a person who is admitted to hospital should be invited to nominate as their next-of-kin a person whom they feel would most accurately be able to speak on their behalf if there was any question of authorising a post-mortem examination. General Practitioners could also record such information in the patient's records (paragraph 82).
- 10 Where a patient has not nominated someone as their next of kin, the hierarchy set out in the Adults with Incapacity (Scotland) Act 2000 and the Mental Health (Care & Treatment) (Scotland) Act 2003 should come into play. We would like to see specific consultation on this point (paragraph 83).
- 11 Fully designed versions of both the child and the adult authorisation forms should initially be piloted through focus groups consisting of parent or family support groups, pathologists and all levels of staff from Intensive Care Units. Those who commented on the forms and leaflets included in the 'Final Report' should also be consulted, and the material should also be open to public scrutiny on the Review Group's website. The Executive should ensure that there is a widespread opportunity for the public to comment on the forms through the advertising of their availability and, if requested, supplying postal copies, as well as placing them on the Review Group's website (paragraph 86).

ISSUES RELATING TO PROCURATOR FISCAL POST-MORTEM EXAMINATIONS

- 12 The Crown Office and Procurator Fiscal Service (COPFS) should some time within the next 12-18 months arrange for an audit of the effectiveness of the arrangements it has now put in place for communication with families. The views of families, as users of the service, must be canvassed (paragraphs 102 and 108).
- 13 There should be a designated person in each area Fiscal's office with the responsibility for dealing with families, along the model of the death unit co-ordinator in Edinburgh. This person would be able to ensure that the final diagnosis was communicated to the family, whether or not the diagnosis had changed, and would be responsible for finding out the family's wishes regarding ultimate disposal of any retained organs. In discussing disposal, they should bear in mind that retention may be an option (paragraph 109).
- 14 This model, or a variant of it, should cover every Fiscal office across Scotland, and the situation closely monitored and audited by COPFS in the interests of consistency of approach (paragraph 110).
- 15 All staff in Fiscals' offices involved in informing relatives of Fiscal post-mortem procedures should have had appropriate training and relevant experience. The potential role of relatives' support groups in providing that training should be borne in mind (paragraph 111).
- 16 In taking forward his work with the Deans of Medical Schools, the CMO should pay particular attention to whether or not training relating to death certification, dealing with the Procurator Fiscal, procedures for cremation and statutory notifications is available, and assess its quality. Any Medical Schools not offering such training should be reminded of its importance, and required to ensure its availability (paragraph 112).
- 17 We support the recommendation in the Consultation Paper on Forensic Pathology to establish a Scottish Advisory Committee for Forensic Pathology (SACFP). That Committee, or another appropriately constituted body, should consider the practice of 'view and grant' post-mortem examinations and develop standards and guidance for its use by appropriately qualified pathologists. There may be an educational and training role for relevant professional bodies such as the Royal College of Pathologists and the British Association of Forensic Medicine (paragraph 118).

- 18 Information on the possibility of organ retention for diagnostic purposes should be included in the more detailed leaflet produced by COPFS, *What Happens When a Death is Reported to the Procurator Fiscal*, as should information on the options open to the family for disposal of organs once these are no longer required for diagnostic purposes (paragraph 119).
- 19 Information about the Cremation (Scotland) Amendment Regulations 2003, which allow for the cremation of body parts retained at post-mortem examination, should be included in the COPFS information leaflets (paragraph 120).
- 20 Information about the potential impact of a defence post-mortem examination should be included in future versions of material which COPFS makes available to relatives (paragraph 121).
- 21 The Review Group is more convinced than ever of the need for the appointment of Bereavement Officers, whose duties should be clearly defined to include speaking to relatives in cases of death in hospital resulting from medical mishap. Until such appointments are made, it is important, once such a death has been reported to the Procurator Fiscal, that there is a clear point of contact in the Area Fiscal's office to whom the relatives can speak. In the meantime, however, hospitals should give immediate consideration as to who should most appropriately discuss such a case with relatives (paragraph 123).
- 22 There is a need for training of hospital doctors about the deaths that require to be reported to the Procurator Fiscal, and for further education of hospital staff about the Fiscal's role in the investigation of deaths. The COPFS leaflet, *Death and the Procurator Fiscal*, is designed to give doctors guidance in this area and should be publicised among medical professionals (paragraph 124).
- 23 The reasons and basis for referring a death to the Fiscal should be recorded by the hospital, to allow a proper audit to be carried out which can identify any inconsistent patterns in referral practice, both within and between hospitals (paragraph 125).
- 24 Responsibility for considering the need for referral to the Fiscal should lie with the consultant and not a junior doctor. The consultant should also take account of the relatives' wishes where the death was clearly natural, in order to avoid causing them further distress (paragraph 126).
- 25 Where information is known about the deceased's attitude towards post-mortem examination, or where it is feasible to make inquiries on the subject, that information should be passed to the Fiscal's office, especially

where the information relates to religious views. Each Trust should therefore liaise with its local Fiscal's office to ensure that procedures are in place for the communication of information about the deceased's attitude to post-mortem examination, where these have been voiced or can be discovered. This information, and details of its transfer to the Fiscal, should be recorded in the patient's medical notes. The police may also have such information, and should always include it in any report to the Fiscal (paragraph 127).

- 26 There need to be agreed guidelines on the writing of death certificates, and there should be further discussion with the Registrar General's Office about the requirements for certification purposes. The working group which the Scottish Executive Health Department is setting up to consider a general revision of burial and cremation legislation should take account of this concern, and of the relevant points made in the Discussion Paper on Forensic Pathology (paragraph 129).
- 27 Consultants should be encouraged to contact the Fiscal if they are concerned about any particular case, rather than simply assuming that it must be referred to the Fiscal. There needs to be greater awareness of the list of cases which *must* be referred to the Fiscal, and those where discretion may be exercised (paragraph 130). Ways must be found of making that list more readily available and accessible. Views should be canvassed on whether the mechanism for doing so should be to include the list in Regulations (paragraph 156).
- 28 Past experience suggests there needs to be closer liaison between, and training of, doctors and Fiscals. The Health Department and COPFS, in conjunction with the Royal Colleges and NHS Education for Scotland, should consider organising joint seminars on a regular basis to promote mutual understanding of medico-legal post-mortem examinations (paragraph 131).
- 29 Families should be given the opportunity to authorise the use of tissue blocks and slides derived from a Fiscal post-mortem examination, in the same way, and for the same purposes, as can be authorised following a hospital post-mortem examination. These tissue blocks and slides are automatically created as a result of the post-mortem examination, and should be retained as part of the medical record. They cannot be used for purposes other than the Fiscal's unless the family has authorised that wider use (paragraph 136). Similar considerations apply to whole organs (paragraph 138).
- 30 Consultation on the report should specifically seek views on who, until Bereavement Officers are appointed, should be responsible for seeking authorisation of the use for education, training, audit and research of material retained at Fiscal post-mortem examination, and the manner in which that authorisation should be sought (paragraph 143).

- 31 When retention for research or educational purposes is desired, the appropriate authorisation form should be used across the country as a whole. The form should be discussed with relatives, who should also be given an information leaflet which explains the purposes of the removal, retention or use (paragraphs 142 and 144).
- 32 There should be specific consultation on whether there are any cases where the interests of justice should allow research to take place on Fiscal post-mortem material without authorisation (paragraph 145).
- 33 The draft standards for Fiscal post-mortem examinations included in this report are commended to the Minister for Health and Community Care, the Lord Advocate and the Minister for Justice to consider how best they can be taken forward. The relevant agencies to which the standards apply should be consulted on the draft with a view to producing an agreed set of standards, for which each can feel a sense of ownership. Arrangements should be made to review performance against those standards (paragraphs 154 and 155).

ETHICAL REVIEW OF RESEARCH PROJECTS INVOLVING HUMAN TISSUE RETAINED AT POST-MORTEM EXAMINATION

- 34 For research involving organs or tissue retained following past practice (i.e. prior to December 2000), Trusts should prepare and make available a statement explaining from what date their local 'consent' forms became effective and made specific reference to research uses of retained organs or tissue. This will assist Research Ethics Committees (RECs) in determining under which practice organs or tissue were retained (paragraph 162).
- 35 For research involving organs or tissue retained between January 2001 and the introduction of the new authorisation forms, RECs should require sight of the local form, so they can consider its quality (paragraph 164).
- 36 Once the standard authorisation forms are in use, RECs should require all research applications to contain a copy of this form (paragraph 168).
- 37 Researchers should report back to the REC on completion of the project with any information about the availability of the results (paragraph 173).
- 38 Changes to the basic structure of RECs stemming from implementation of the EU Directive on Clinical Trials provide an ideal opportunity to review membership and training opportunities (paragraph 175).

CHAPTER 1 INTRODUCTION

PREVIOUS WORK

- 1 The 'Final Report' (as it was called) of the Review Group was published by the then Minister for Health & Community Care, Susan Deacon MSP, on 23 November 2001.
- 2 The basic principles underpinning our work were and are that legal controls over what happens to a child's body after death should be firmly located with the bereaved parents themselves, and that the competently expressed wishes of an adult or a mature child in life should take priority over the views of relatives after his or her death.
- 3 Key recommendations of the report included:
 - a root-and-branch overhaul of the 1961 Human Tissue Act covering post-mortems and organ retention. In the view of the Review Group, this requires a repeal of the current law and a new stand-alone piece of legislation;
 - all hospital post-mortems to be authorised by relatives, including whether any organs are to be removed and for what purpose;
 - clarification of the right of an adult to make a legally binding disposition of his or her body after death, and a radical re-assessment of who should have the power to speak on behalf of that person where no expressed wishes have been left;
 - a penalty to be imposed on those who breach the provisions of that authorisation, or who act without authorisation;
 - a stronger monitoring and policing role for research ethics committees, underpinned by legislation;
 - the promulgation of new information leaflets to be available to families on all of the issues relating to hospital post-mortem examinations and the subsequent use of organs or tissue;
 - the development of authorisation forms, one for adult hospital post-mortem examinations and one for post-mortem examinations on children, for use across Scotland, spelling out all of the options available, but also taking account of the sensitivities of those who do not want to know the details of the post-mortem examination and/or the proposed use of organs or tissue;

- and, reflecting the genuine desire of bereaved parents to protect valuable medical research, an agreement that significant but non-destructive research on retained organs should be permitted 6 months after the start of the formal 5-year organ reclamation period.
- 4 We saw the report as representing a radical step forward in redressing the balance of rights and responsibilities among the medical profession, patients and their families, or those closest to them. The law as it stands is vague and uncertain. It is confusing for relatives – but also for doctors and other relevant healthcare providers. After extensive consultation with families and others, the Review Group felt strongly that this more than 40-year-old piece of legislation required a thorough overhaul.
 - 5 In our Preliminary Report (January 2001), we spoke of the need for parents to be consulted properly after a child’s death, before any hospital post-mortem examination was carried out. We were encouraged then, and remain encouraged, by the willingness of the Government, of the NHS and of the medical professions to implement our recommendations. If this whole issue is to be properly addressed, so that the medical profession can carry out hospital post-mortem examinations and research within a clear legislative framework, we must take a further step.
 - 6 A radical shift away from ‘absence of objection’ to hospital post-mortem activity and organ removal towards the need for active ‘authorisation’ by parents is needed, as well as a recognition that adults’ competent wishes about what should happen after their death should not be thwarted by the views of their relatives.
 - 7 We were clear that making this change would require very fundamental alteration to the existing legislation. Indeed, in our view it is necessary that the current legal regime is scrapped and replaced with one that is coherent, consistent, principled and clear.
 - 8 We were anxious that our report should not be seen as an attack on medical research. It was not. Indeed, we were encouraged by the attitudes of those we consulted in this respect. For example, it was clear that the vast majority of parents to whom we spoke, and whose children had organs retained without proper authorisation in the past, recognised the potential value of medical research. In recognition of this, our report incorporated a proposal from the majority of the family groups that limited medical research should be allowed on organs which had been retained under past practice – even during the dedicated 5-year reclamation period (see paragraph 22 below).

- 9 In respect of bereaved parents, we expressed the hope that the report would be an opportunity for many of them to achieve a sense of closure. They have been driven by the need to make sure that organs will never again be removed from a child and retained without proper authorisation. Improvements in the law and clear rights for every parent must be the legacy of their work and commitment.
- 10 While making clear that the report was being published for consultation, the Minister drew attention to a number of measures and recommendations on which she wanted to see immediate action. The effectiveness of the information leaflets and standard authorisation forms for relatives both needed to be tested, and the Executive would consult the NHS and patient groups on the new leaflets. The use of the new paediatric authorisation form would be piloted in children's hospital settings in Lothian.
- 11 Before dealing with the work we undertook in Phase 3 of our existence, we look first at the range of work undertaken by other agencies to take forward our recommendations.

AUDIT SCOTLAND VALIDATION OF ORGAN NUMBERS

- 12 In fulfilment of one of the recommendations in our Preliminary Report, the Minister for Health & Community Care requested Audit Scotland to undertake an exercise to validate the information provided by Trusts during the initial phase of the Review Group's work. In addition, Audit Scotland was asked to:
 - examine the reasons for retention;
 - provide a breakdown of the number of hospital and Fiscal post-mortem examinations;
 - review the systems to record all materials held, including tissue blocks and slides;
 - discuss findings with the Review Group and parents' support groups to give them an opportunity to comment on the shortcomings of existing systems and the way forward.
- 13 The Audit Scotland review aimed to establish not only the number of organs retained but also the robustness of hospital information systems, to ensure that a relative making an inquiry would be provided with comprehensive and accurate information about any organs retained at post-mortem examination. The review was carried out in all Trusts in Scotland which provide a pathology service. Audit Scotland tested the systems in place for

ensuring that relatives' inquiries could be dealt with efficiently and effectively. These tests involved physically tracking from retained organs to records and any other associated tissue held and from post-mortem examination records to retained organs, tissue blocks and slides. Audit Scotland also surveyed Trust Chief Executives and Medical Directors on a range of issues surrounding organ retention.

- 14 It proved difficult for many Trusts to provide analyses of post-mortem examinations by age group and by type (hospital or Fiscal) over the full period 1948–2000, because this required them to refer to manual systems. Computerised systems have been put in place only in the last 10 years. The data reported on included organs retained from Fiscal post-mortem examinations performed in NHS settings. We return to the question of data, both in relation to hospital and Fiscal post-mortem examinations, later in this report.
- 15 In terms of storage, Audit Scotland found that all Trusts had taken steps to ensure that retained organs were kept in specially designated areas only. There were concerns about the need for national guidance on the physical storage of tissue blocks and slides, and this has been addressed as part of the clinical standards devised by NHS Quality Improvement Scotland (see paragraph 25 *et seq* below).
- 16 While systems for identification of organs, tissue blocks and slides varied, all Trusts were, in Audit Scotland's opinion, able to demonstrate rigorous systems for identifying retained organs, tissue blocks and slides. In every situation, the review team's tests showed that even archived information could be obtained without significant difficulty.
- 17 The report, which was published in March 2002, noted that, in accordance with our recommendations, every Trust had nominated a named point of contact to manage inquiries from relatives and had rigorous systems for dealing with those inquiries. At the time of the Audit Scotland report, more than 2,000 inquiries had been made. In a small number of these, Trusts had had difficulty in responding timeously, particularly where the inquiries related to deaths up to 40 years previously. Factors such as hospital closures and Trust reconfigurations limited the ability of Trusts to respond. Trusts expressed regret about the small number of mistakes made in the past, where wrong information had been passed to relatives, leading to distressing and sometimes acrimonious situations. All Trusts were, however, able to demonstrate systems which should prevent these problems arising in future.

- 18 The Audit Scotland report showed that 10,862 organs were being held in Trusts across Scotland, compared to the 7,886 declared to the Review Group. Most of the difference was accounted for by the inclusion by Audit Scotland of museum and archive collections. Inevitably, when the report was published a great deal of attention focused on the numbers. We believe, however, that the key issue in this area is the ability of Trusts to deal sensitively and fully with inquiries from each family which wishes to investigate whether it was affected by past practice. Audit Scotland concluded that that all Trusts had put in place rigorous systems for identifying retained organs, reports and associated tissue blocks and slides. It also felt that it could be confident that inquiries could now be dealt with effectively, by which it meant in a way that would avoid additional distress to relatives. Some Trusts were retaining organs until the law on cremation of body parts was clarified, and this has now been done (paragraphs 34–37).

5-YEAR CAMPAIGN

- 19 On the strength of the assurances in the Audit Scotland report, the Executive felt able to implement the recommendation from our Preliminary Report that a start could be made to the formal 5-year period during which families are entitled to reclaim organs, tissue blocks or slides retained under past practice. The decision was taken only after detailed instructions had been prepared, with input from family support groups, to help staff in Trusts deal with inquiries.
- 20 The 5-year period began on 18 April 2002, with notices in national newspapers designed to help families decide whether or not they wished to investigate the possibility that their relatives' organs had been retained under previous post-mortem practice. Two linked public notices highlighted the steps to be taken by, and the information available to, those wishing to investigate. An NHS Helpline (08000 27 00 09), with details of freephone local telephone numbers, has been set up as part of the campaign, and copies of an advice leaflet have been made available to every health centre in Scotland. The information can also be found on the Internet: www.show.scot.nhs.uk/sehd. The campaign was put together following discussions between various interested groups, including families, family support groups, health professionals and NHS staff who have a background in the issue of organ retention. A very small number of new enquiries were generated as a result.
- 21 We recommended that organs and tissue unclaimed at the end of the 5 years should be legally deemed to come under the authority of the relevant hospital, which should be able to make use of it for legitimate research or

educational projects. Alternatively, where organs and tissue were not considered necessary or suitable for those purposes, the hospital should ensure their respectful disposal. This approach has the additional benefit that the material could be available for return to families even after the expiry of the 5-year period. This recommendation found general acceptance.

RESEARCH

- 22 The consultation on our 'Final Report' specifically included the question of research involving organs and tissue retained under past post-mortem practice. There was strong support for the arrangements set out in the consultation letter. These had been agreed with the family support groups with whom the Review Group worked, and were: that there should be no moratorium on existing research involving organs and tissue retained under past post-mortem practice, including Fiscal post-mortems; and that new research projects could begin 6 months after the start of the 5-year period during which families are entitled to reclaim these organs or tissues. As the 5-year period began on 18 April 2002, new research projects have been able to start since 18 October 2002. In accordance with our recommendations, all such projects must be non-destructive, and be likely to make a significant contribution to diagnosis or therapy.
- 23 The current Minister for Health & Community Care, Malcolm Chisholm MSP, indicated that he was aware that a small number of parents would find this decision distressing. He encouraged them to make sure that they contacted either the NHS Helpline or their local Trust to register their objection to any material retained at a post-mortem examination on a child of theirs being used for research purposes. This is a decision that each family must take for itself.
- 24 While families have made clear all along their support for research, we are in no doubt that research on material retained at post-mortem examination can only be undertaken in future if it has been authorised either by the deceased or by the relatives. That approach is reflected in the authorisation forms for paediatric and adult hospital post-mortem examinations included in this report, and in the form, also included, which has been devised to allow the authorisation for research (as well as education and audit) of material originally retained following a Fiscal's post-mortem examination, but no longer needed for the Fiscal's purposes. As a further safeguard, we set out in Chapter 4 the criteria we have devised to guide Research Ethics Committees in their use of organs and tissue derived from post-mortem examinations.

CLINICAL STANDARDS

- 25 Our Preliminary Report contained the recommendation that the Clinical Standards Board for Scotland should be encouraged to incorporate a standard relating to the post-mortem examination process in its generic standards, as the most effective way of monitoring implementation of our Code of Practice for hospital post-mortem examinations.
- 26 Following consultation with the Board, which now forms part of NHS Quality Improvement Scotland, we agreed that in order fully to address the issues we had identified, a Project Group on Standards for the Management of Post-Mortem Examinations should be established to take this forward, rather than incorporating a single standard into the generic standards. The remit of the Project Group was to:
- Develop robust standards for the following in relation to the management of hospital post-mortem examinations:
 - Pathology practice - hospital post-mortem examinations;
 - Authorisation and information;
 - Storage, handling and disposal;
 - Record-keeping;
 - Education
 - Recommend a review process; and
 - Provide a baseline report.
- 27 The Project Group, established in August 2001, included healthcare professionals and representatives of family support groups. Draft Standards were published in March 2002, and two open meetings were held - in Glasgow and Dunblane - in April 2002. These were followed in May 2002 by two pilot visits to test the measurability of the standards. After this period of consultation, the Project Group carried out a comprehensive revision of the standards in the light of the valuable feedback received. The final standards were published in March 2003. NHS QIS is currently undertaking visits to peer review performance against the standards.
- 28 We particularly welcome the fact that the standards make use of our concept of 'authorisation', and that they point to the introduction in due course of the standard forms and information leaflets on which we have been working.
- 29 The section of the standards document dealing with the over-arching principles of post-mortem examinations makes a number of points which have a direct bearing on our Phase 3 work. The NHS QIS Project Group

recognised that post-mortem examinations carried out by the Fiscal service were outwith its remit. In response to views which were strongly expressed during the process of devising the standards, the principles have however been highly commended to the Crown Office. We report in Chapter 3 on the work we have undertaken with the Crown Office and Procurator Fiscal Service to adapt these standards for use in the context of Fiscal post-mortem examinations. These standards are attached as Appendix 2.

- 30** The NHS QIS Project Group adopted our recommendation that tissue samples should be regarded as part of the medical record so that they remain available for additional testing in the future. This assumption is, of course, dependent on the fact that their absorption into the medical record is explicitly authorised when authorisation for a post-mortem examination is given. We believe that, in Fiscal cases, the position is not as clear in law as it might be, and discuss this issue further below (paragraphs 132-145).
- 31** The NHS QIS standards document also recognises the need for a review of the whole clinical pathway of care for the deceased and their relatives, and the Project Group therefore welcomed the Executive's commitment, as set out in its response to the final report from the Bristol Inquiry, to strengthening the support which NHSScotland provides to families when a bereavement takes place. In this third phase of our work, we have seen a strengthening of our own support for the concept of Bereavement Officers. The then Minister re-iterated her support, when publishing our 'Final Report', for 'bold and radical measures to ensure that families get the support they need from the NHS when bereavement takes place, particularly where that involves the loss of a child'.
- 32** The NHS QIS Project Group also noted that end of life issues, including post-mortem examinations, must be covered in the medical curriculum for doctors in training, and pointed out that the Chief Medical Officer was taking this forward with the Deans of the Medical Schools and Trust Medical Directors.
- 33** The Review Group reported concerns to the Chief Medical Officer about the degree to which the promised changes to the culture within NHSScotland were taking place. There still seemed to be a lack of involvement on the part of consultants in approaches to families about hospital post-mortem examinations, and post-mortem examinations seemed to have disappeared from the Medical Schools' curricula, with the exception of Edinburgh. The Chief Medical Officer has indicated that he is considering with the Deans of the Medical Schools, Trust Medical Directors and NHS Education for Scotland what further work should be undertaken. Since

communication skills are an essential attribute which all consultants should possess, especially in relation to the breaking of bad news, he proposes to use issues relating to hospital post-mortem examinations as a focus for implementing the recommendations in the document *Talking Matters*. This has been produced by the Centre for Change and Innovation as a means of improving consultants' communication skills. We understand that the Chief Medical Officer also intends to set up a working group to develop an information pack containing essential documents relating to the end of life, which would have practical value as well as being used to help encourage the skills of doctors in training in relation to bereavement. We welcome these developments.

CREMATION REGULATIONS

- 34 One of the most distressing problems of past practice, which we highlighted in our Preliminary Report, was the difficulty that many relatives faced when trying to dispose of organs, tissue blocks and slides in a manner which they felt was fitting. If they asked the hospital to do so, Health & Safety Regulations led to the material having to be disposed of as clinical waste, a state of affairs which hospitals themselves very much regretted. Where relatives reclaimed organs for disposal, they then found that most crematoria took the view that the Cremation (Scotland) Regulations 1935 did not give them clear authority to cremate body parts.
- 35 We recommended that any legal and administrative barriers to the disposal of organs, tissue blocks and slides should be removed as soon as possible. The variable nature of the arrangements across Scotland was particularly unacceptable. We were pleased that our work triggered and informed the amendment of the 1935 Regulations. The Cremation (Scotland) Amendment Regulations 2003, which came into effect on 27 June 2003, enable the cremation of body parts of a deceased person, following removal at post-mortem examination, whether by hospital or authorised by the Fiscal. In announcing this significant change to the law, the Minister for Health & Community Care said:

In bringing forward these regulations, we have taken positive steps towards alleviating any unnecessary delay or stress on families who wish to arrange for cremation of the remains of a loved one. The development of the Regulations was based largely on what families told the Review Group about the problems they had been encountering. I am pleased we are now able to go some way to address their circumstances.

36 The regulations:

- prohibit the cremation of body parts unless the Medical Referee is satisfied that the parts were removed in the course of a post-mortem examination carried out on the deceased, that the death has been duly registered, and that a proper application for the cremation has been submitted; and
- provide, that in cases where the Medical Referee cannot be satisfied of such matters, Scottish Ministers may still authorise the Medical Referee to allow the cremation of body parts.

37 We believe that these changes will help to address some of the obstacles the Review Group heard were causing distress to relatives. Respectful disposal has now become a real option for families.

GENETIC TESTING

38 The ‘Final Report’ drew attention in paragraph 29 to the difficulties which can arise if the information gained from a post-mortem examination discloses a condition which is inheritable. Paragraph 33 drew attention to concerns in the case of mature children and adults about the potential implications of genetic information. The report also discussed at paragraph 117 issues about research which results in the availability of genetic information. These points were drawn to the attention of the Human Genetics Commission in a letter of 8 May 2002.

39 That letter coincided with the publication of the Commission’s *Inside Information* report on the use of personal genetic information. At a meeting of the Commission in September 2002, the Department of Health/Welsh Assembly Government’s consultation document *Human Bodies, Human Choices* and the Review Group’s concerns were discussed, but the Commission concluded that it should respond formally to the consultation document only and not to the Review Group. The overall conclusion was that the matters raised by the Review Group were extremely relevant to the ongoing review of the relevant legislation and supporting Codes of Practice. The Commission expressed the hope that *Inside Information* would prove useful, for example, in respect of the principles that it established of an “entitlement not to know”, or the concept of “benevolent intent” regarding testing after death. The Commission also commented on the sensitivities around ownership of human tissue used in research, but concluded that this was best dealt with in individual cases by research ethics committees or oversight bodies.

- 40 Following the letter from the Review Group, the Commission noted that it had also been asked to consider several other sensitive matters, such as consent from families for genetic testing as part of the coroner's post-mortem examination of a sudden infant death. The Commission says that it has proved extremely difficult for it to provide anything other than very general advice in such cases, because the law is far from clear and the individual circumstances are both unusual and highly charged. The Government has now responded to the Commission's report in its recently published Genetics White Paper and an accompanying Open Letter. These are available at www.doh.gov.uk/agencies.
- 41 The Review Group has written again to the Chair of the Commission seeking a more specific response to the questions we have asked. This letter points out that the Review Group intends to treat the question of genetic information no differently from any other kind of information, and asks for the Commission's views on this approach. We also touch on the subject of genetic testing in paragraph 81 below.

DEVELOPMENTS ELSEWHERE IN THE UK

- 42 Publication in May 2003 of the 'Isaacs Report', *The Investigation of Events that followed the death of Cyril Mark Isaacs*, shed light on a hitherto unexplored aspect of past post-mortem practice: the unauthorised retention of brains from Coroners' autopsies for research purposes. The Review Group has not been asked to undertake a specific investigation of the position in Scotland, but Audit Scotland was able to make clear the number of brains retained in Scotland. This information is now in the public domain, and reflects in part the important research work being undertaken in Scotland on conditions such as Alzheimer's disease and CJD. It cannot therefore be assumed that retention of these brains was unauthorised in every case. The publicity surrounding the publication of the Isaacs Report was comparatively muted, however, perhaps because this was an issue mainly affecting adults. It nevertheless underlines the importance of ensuring that all research use of any organs derived from post-mortem examination is properly authorised.
- 43 We have maintained links with the Retained Organs Commission in England and Wales, partly to ensure as consistent an approach as possible across the UK, but also to ensure efficiency of response in the small number of cases involving families who have moved from one side of the border to the other since the time when a post-mortem examination was carried out on one of their relatives.

FAMILIES' ATTITUDES AND EXPERIENCES

- 44 While we are aware that a small number of families feel that their inquiries have not been dealt with fully, and that legal actions are pending against Trusts as a result of organ retention, our overall impression is that most families who wished to investigate the issue have already done so and that there is unlikely to be any sudden or large increase in the number of inquiries which will be made of Trusts. We also believe that in general Trusts' handling of inquiries is not adding unnecessarily to families' distress, and the range of work already described has indicated how seriously everyone involved takes the need to avoid a recurrence of past practice. **Even so, we believe that the arrangements for dealing with inquiries must remain in place until the end of the formal 5-year period mentioned in paragraph 22, i.e. until 17 October 2007.**
- 45 While the number of hospital post-mortem examinations continues to remain low, we draw encouragement from data published on 30 July 2003 in response to a Parliamentary Question tabled by Des McNulty MSP. He had asked how many brains and other organs had been retained by hospitals in the previous 12 months. The Answer provided a figure for each Trust, but noted in the case of Lothian University Hospitals NHS Trust that the 37 other organs which had been retained, mainly hearts, reflected the practice of retaining organs for a short period (between one and several weeks) as part of the active pathology teaching programme included in the medical curriculum of the University of Edinburgh College of Medicine and Veterinary Medicine. The authorisation of the relatives for the use of these organs in medical education had been obtained in every case. We highlight these data here in the hope that they will encourage staff in other hospitals to take a more confident attitude to approaching relatives for their authorisation of a hospital post-mortem examination. We also hope that the new authorisation forms will further encourage such attitudes.

NEW LEGISLATION

- 46 We know that for many families a change in the law is the guarantee they require that there will be no repetition of past practice. We therefore welcomed the assurance which the Minister for Health & Community Care gave to the Parliament's Health & Community Care Committee in his letter to them of 5 February 2003: "I have made clear my personal support for the Review Group's recommendations that the 1961 Act should be repealed, and that the legislation which replaces it should be based on the fundamental principle of ensuring that the competently expressed wishes of the deceased are carried out wherever possible." Families have been patient, but we hope that when an announcement is made of the legislative programme for the second year of this second session of the Parliament, it will contain details of new legislation on the retention of organs at hospital post-mortem examination.

47 When our 'Final Report' was published, we made clear our preference for legislation to be produced which would cover the entire United Kingdom. However, we were also clear that if necessary the Scottish Executive had the authority to proceed with legislation specifically designed for Scotland. Since then, the Department of Health and the Welsh Assembly Government have published *Human Bodies, Human Choices* (July 2002), and the outcome of that consultation. We regret that the other Health Departments have chosen not to adopt our concept of 'authorisation' for reasons which appear to us to be unconvincing. We also note that they have decided to include in the same legislation issues concerning both organ retention and organ transplantation; a decision which found no favour with the Review Group. We remain concerned that there should be as much consistency as possible between the two systems of legislation, for the sake of families and health professionals, but reiterate our view that 'authorisation' is a preferable concept to that of 'consent', and our commitment to our other recommendations. In particular, the Review Group does not believe it to be appropriate that new legislation should contain provisions dealing both with transplantation and retention of organs.

REMIT FOR PHASE 3

48 As a result of the Minister's consideration of the responses to the formal consultation on our 'Final Report', he announced on 19 July 2002 that he had decided to ask the Review Group to remain in existence for a further year. He felt that, while a great deal of work had already been taken forward, the Review Group was best suited to oversee some of the particular recommendations, including:

- further development of the standard leaflet and authorisation forms for hospital post-mortem examination, to make sure that they are easily understandable and take full account of the practical needs of families and hospital staff;
- working with the Crown Office and Procurator Fiscal Service to address issues concerning the relationship between hospital post-mortem examinations and those instructed by the Procurator Fiscal, with particular emphasis on how the standards for hospital post-mortems being developed by NHS QIS might be adapted to suit the circumstances of Fiscal post-mortem examinations; and
- considering how best to provide an ethical review of all research projects involving human tissue retained at post-mortem examination, until the legislation putting research ethics committees on a statutory basis is in place.

- 49 The Review Group itself has held 7 meetings during Phase 3 of its work. It also set up 2 sub-groups, one to take forward the work on authorisation forms and information leaflets, the other to look at issues related to Fiscal post-mortem examinations, especially those instructed following a death in hospital. Details of the membership of the Review Group and its sub-groups are given in Appendix 1.

CHAPTER 2 AUTHORISATION FORMS AND LEAFLETS

COMMENTS FROM CONSULTATION

- 50** The consultation exercise on the Review Group's 'Final Report' showed general support for the concept of standard information leaflets and authorisation forms, and for separate forms for adult and paediatric post-mortem examinations. The BMA and the Royal College of Pathologists approved in particular of the fact that the adult form had tackled a deficiency in current models in seeking to make sure that any wishes expressed by the deceased should be given proper weight. The Scottish consultant neuropathologists suggested that there should be a completely separate form for those who do not wish any information about the post-mortem process.
- 51** Overall, however, the general opinion was that the previous version of the information leaflet was too long and detailed, and was intelligible only to those of fairly high academic attainment. A number of respondents suggested that there should be two leaflets, the first in question and answer format, with a second leaflet giving a more detailed description of the post-mortem process for those who wished that further information.
- 52** The authorisation forms were also criticised by everyone who responded on this issue as being too detailed and cumbersome and likely to be seen as intimidating by recently-bereaved relatives. These views were echoed by the NHS QIS Project Group on Hospital Post-Mortem Standards, and were also made at the two open meetings at which the draft standards were discussed.
- 53** Arrangements were made for the paediatric authorisation form to be piloted by Lothian University Hospitals NHS Trust. However, initial discussions amongst the clinicians led them to pilot the forms in 'mock' interviews with midwives and previously-bereaved parents who were willing to take part in the study. The clear view was that the form was too long and complex to be acceptable or useful in the acute stress of bereavement, and the Trust therefore felt unable to move to the next stage of using the forms with newly-bereaved parents. There was no piloting of the adult version of the form.
- 54** Against that background, a sub-group was set up with the following remit:
- taking account of the comments received during the consultation process, to further develop a standard information leaflet and authorisation forms for hospital post-mortem examination which take full account of the practical needs of families and hospital staff; and
 - to make arrangements for piloting both the adult and paediatric authorisation forms.

- 55 In taking this work forward, the sub-group would be expected to consider the examples of more recent forms developed by the BMA and Lothian University Hospitals NHS Trust and any others which might be drawn to its attention. It should also take account of the work of the Department of Health in London (DH) on consent forms.

AUTHORISATION FORMS

- 56 The sub-group took as its starting point the Review Group's requirement that there had to be absolute clarity about what was being authorised, and that the forms should be capable of being produced in triplicate, with one copy given to the family, one retained in the medical records and the third copy given to the pathologist. At the same time, the forms needed to be user-friendly. There also needed to be separate forms for children and adults. The sub-group did not underestimate the difficulty of producing forms which would be intelligible to the public but which would also provide the health professionals with the clear mandate they need.
- 57 In order to draw on best practice, the sub-group asked each Trust to provide a copy of its current post-mortem examination consent form, along with a note on whether these had been piloted with focus groups, and information about Trusts' experience of using the forms. The Department of Health also provided a copy of the draft consent forms it was then in the process of devising. A copy of the consent form in use at the Boston Children's Hospital, USA, was also obtained for purposes of comparison. Further consideration of the experience of other countries was considered impractical, although the sub-group was shown a presentation prepared by Dr Irene Scheimberg, Senior Lecturer in Paediatric and Prenatal Pathology, University of London, which indicated that in most other countries consent forms were generally one or two pages at most. The consultations undertaken by the Department of Health also emphasised the importance of clarity and brevity.
- 58 After making comparisons of all the available models, the sub-group selected the DH forms as its starting point. It felt that this would also help to promote consistency of approach across the UK. In the event, the layout of the forms changed considerably during the course of work on them. This was in part to take account of the differences in approach, for example in relation to the concept of 'authorisation'.
- 59 The sub-group has produced the following documents:
- a form for the authorisation of a hospital post-mortem examination on a child;
 - a leaflet giving basic information about such a post-mortem examination;
 - a leaflet giving more detailed information about such a post-mortem examination;

- a form for the authorisation of a hospital post-mortem examination on an adult;
- a leaflet giving basic information about such a post-mortem examination;
- a leaflet giving more detailed information about such a post-mortem examination; and
- a guide for professionals to help them through the various forms and leaflets.

60 The Review Group also worked on standard forms for the authorisation of use of material retained at a Fiscal post-mortem examination for purposes of research, medical education or audit, once the Fiscal has indicated that the material is no longer needed for his/her purposes. These forms are considered in the next chapter of this report.

61 The text of all of these forms and leaflets can be found in Appendix 3 to this report.

62 The child form is intended to fulfil the Review Group's overarching aim of placing control with the parents. Section 1 establishes that they are the ones with the power to give authorisation. The first option offered is to authorise a **full** post-mortem examination, in the knowledge that this will involve keeping small tissue samples which will form part of the medical record and which may be used for purposes of medical education, training, research and audit. This is intended to shorten the form and reduce the burden on parents by making it unnecessary to include a section for each of these specific purposes, while at the same time making clear what can be done with these tissue samples.

63 There was considerable discussion within the sub-group and the Review Group itself on whether the forms should provide for separate and specific authorisation of the *research* use of the blocks and slides kept as part of the medical record. In the event, the Review Group has taken the view that it set out the position sufficiently clearly in paragraph 74 of its 'final report':

We further recommend, in common with the Alder Hey report, that once a properly informed decision has been made to authorise a post-mortem examination, interests in the prepared blocks and slides should pass to the hospital authority, who may retain and use them for proper study and research purposes. This recommendation is also in line with those of the Nuffield Council on Bioethics.

As far as we are aware, no-one took issue with this statement during the consultation on our previous report. It is also consistent with NHS QIS Standard 3 (Storage, Handling and Disposal), the rationale for which says 'Glass slides and tissue blocks should also be retained for the following valuable purposes: . . . for research purposes.'

- 64 If this report is published on a consultative basis, **we recommend that this point (whether there should be an authorisation for research separate from that for medical education, training and audit) should be clearly identified in the consultation letter, since it is essential that the forms command the support of both relatives and health professionals.**
- 65 The hospital must use the medical record within the general constraints of the Data Protection Act 1998, the Human Rights Act 1998 legislation and subject to the general common law principles governing confidentiality, and any research involving the medical record must be subject to approval from a Research Ethics Committee.
- 66 The second option is for parents to authorise a **limited** post-mortem examination, with clear instructions as to the way(s) in which the examination is to be limited.
- 67 The third choice is for parents of babies or very young children to authorise an **external** post-mortem examination. By this is meant an investigation which does not require an internal examination, but is something more than simply observing the body in order to write a death certificate (the process known as ‘view and grant’ in forensic cases). There is value in a paediatric pathologist examining a baby externally, particularly a stillborn fetus which may not have been seen by an obstetrician. The parents can authorise an X-ray or ultrasound examination or even a skin biopsy, which might give a chromosome result. These, together with the external examination and assessment of the placenta, can potentially yield a lot of useful information about the death, as well as possibly providing guidance for advising in future pregnancies. The form itself does not explain that this is likely to yield less information, though the information leaflet does. The sub-group felt that inclusion of this information on the face of the form could be seen as an attempt to influence parents’ decisions. The process is more impartial if this is explained in the leaflet or by the person completing the form.
- 68 Section 2 allows the parents to authorise the retention of whole organs for further examination, as well as for purposes of medical education, training, audit and research. The sub-group understood that it was only in a small number of cases that whole organs need to be retained. However, it felt that, because of the emotional significance of whole organs to many families, this aspect of the post-mortem examination needed to be the subject of separate authorisation.
- 69 Section 2 also sets out the options open to the parents once the whole organs have been subject to detailed examination. These are:
- for them to be returned to the body, although on the understanding that this might delay the funeral;

- for the hospital to dispose of the organs;
- for them to be collected by a funeral director and disposed of according to the parents' wishes; or
- for the organs to be gifted for purposes of medical education, training, audit and/or medical research. The use of the term 'donation' has been avoided in this context to avoid confusion with organ donation for purposes of transplantation.

70 Section 3 of the form allows the parents to mention any requests or impose any conditions on the retention or future use of the organs, tissue blocks and slides. These will be recorded on the form.

71 The form then provides for the signature of the member of hospital staff witnessing the authorisation. This will in most cases be the member of staff who has taken the parents through the form. Parents should be offered information as a matter of course. Where they choose to receive it, the details of what has been provided should be recorded, so that there will be no doubt in future about the nature of the information given. The parents would then sign the form.

72 It will be noted that there is a box in the 'witness' section to cover the situation where only one parent or guardian is present. The sub-group took the view that it would be appropriate to proceed on the basis of the authorisation of one parent where only one parent was normally in contact with the child, or where there were compelling reasons for the post-mortem examination which outweighed the objection of only one of the parents. The sub-group, however, accepted that there could be difficulties if a parent who was present authorised the post-mortem examination and subsequently the other parent, who had not been present, objected. The sub-group felt it was reasonable that, where only one parent was present to give authorisation, that would normally be sufficient to proceed, and a pathologist performing a post-mortem examination on that basis should be protected in law. When authorisation is being sought, enquiries should be made as to whether the absent parent would be likely to object. If it appeared likely that there would be disagreement, ordinarily the post-mortem examination would not take place until further enquiries were made of the absent parent or legal advice taken. Where both parents were present but could not agree on whether to authorise the post-mortem examination, the examination should not go ahead.

73 This is highly sensitive territory, and **the Review Group would wish to see wider views canvassed on the approach outlined in the previous paragraph.**

- 74 The sub-group noted that there might be some limited circumstances in which the pathologist may wish to remove tissue additional to that required for the post-mortem examination, for example as part of an approved research project. Specific authorisation for this would be needed, and this must be recorded on the form.
- 75 The adult authorisation form follows the same pattern as the form for a post-mortem examination on a child, except that it draws attention to the need for the person giving authorisation to alert the hospital staff to any instructions which the deceased might have left in respect of post-mortem examination. In this context, it would be good practice to make sure that any wishes expressed by the deceased were clearly recorded in the medical notes and placed prominently in those notes. A system, for example, of labelling a folder which includes notes containing this type of advance directive should be devised to make such cases easier to identify. The right of the individual to make provision in advance for the use to which his/her body may lawfully be put is in part reflected in the Anatomy Act 1984, which allows an individual to donate his/her body after death for dissection. Our approach proceeds from the assumption either that this authority is wide enough to cover decisions about post-mortem examinations also, or – failing which – that the decision to pre-authorise post-mortem examination or removal and retention of organs or tissue takes the form of an advance directive, which, if applicable in the circumstances, is generally agreed to have lawful force. It should be noted that advance directives need not be in written form to be lawful. Indeed, in our ‘Final Report’ we made the point in paragraph 29 that we could see no justification for requiring written evidence of the wishes of the deceased. This recommendation is in line with our earlier comments.
- 76 A further difference in the adult authorisation form is that the notes for hospital staff discuss the possibility of the deceased’s nominated representative or nearest relative granting permission over the telephone for another person to give authorisation. The sub-group noted that this was a possibility in forms used in the USA. The reason for this is that the nominated representative or nearest relative may be unable or unwilling to attend the hospital. As the form recognises, this would only be done in exceptional circumstances. Any such discussion would also have to be witnessed by another member of staff. By and large, the Review Group does not believe that over-the-phone authorisation should be acceptable, but **recommends that this approach should be the subject of wider consultation.**

- 77 The sub-group felt strongly that the presentation of the forms and leaflets required careful consideration, in particular to avoid giving people more information than in fact they wish to receive. It therefore decided that there should be an Information Pack consisting of an A4 folder with a pocket on the right inside cover which would contain the authorisation form and the level one information leaflet. The front of the pocket on the inside of the folder would be left blank so that each hospital had a space in which to insert local contact details. On the inside left of the folder there would be a list of the key points for parents or relatives, including key points about the post-mortem examination. In particular, the summary would explain that:
- more detailed information was available, if required, in the level 2 leaflet, which should be published separately and not included automatically as part of the Information Pack;
 - relatives should ask as many questions as they wish, and take as long as they need to reach a decision;
 - relatives need to make a decision about the kind of post-mortem examination – if any – which is most acceptable to them, and about whether or not they wish organs to be retained and for what purposes;
 - relatives could change their mind at any time, so long as the post-mortem examination had not already been carried out.
- 78 The sub-group believed that it was appropriate to devise two information leaflets containing different levels of information. The first, level 1, information leaflet, which would be offered as a matter of course, is intended to provide answers to the kind of practical questions families are most likely to ask. The second, level 2, information leaflet gives more detailed information (for those who wish to know more) about the post-mortem examination itself, and the reasons for wishing to undertake it. It also contains information about the retention of organs, since the relatively small number of cases in which this is considered necessary would not justify including this information in the level 1 leaflet. The sub-group recognised that not every family would wish to read through even the level 1 information leaflet, and there is no requirement that they should do so. The forms allow the post-mortem examination to be authorised once the person feels he or she has received enough information to do so. While there are certain questions on the form that must be answered, making inevitable the receiving and considering of a certain amount of information, the overall intention is that information should be offered and received to the extent that the family wishes to have it.

- 79 Although every effort has been made to keep the forms as simple as possible, it is not easy to reconcile that aim with the need to be sure that families have been made aware of all of the options. This underlines the importance of an informed member of the hospital staff being on hand to take the family through the form. While the Review Group has indicated in previous reports that – under the current regime – this should, where possible, be someone already known to the family, the need to have a member of staff available also reinforces the importance of creating, as a priority, a cadre of Bereavement Officers across NHSScotland. In addition, however, all hospital staff who are likely to be involved in seeking authorisation must be properly trained, and the authorisation forms should act as a focal point for that training. Such training might include a video prepared for staff, as well as the guidance for professionals which we have already developed. The video might be based on a simulation of the process of taking parents through the form, which would give an opportunity for the parents’ support groups to participate in the training programme. **The Review Group recommends that the Chief Medical Officer should explore this with the Deans of Medical Schools, Medical Directors, the Royal Colleges and NHS Education for Scotland. Such training programmes should also take account of others being developed elsewhere in the UK, although allowance would have to be made for the differences of approach reflected in the forms being used.**
- 80 The Review Group accepts that, as well as training of hospital staff, there needs to be greater public awareness of the hospital post-mortem examination process. **It recommends to the Executive that it should explore the possibility of developing an equivalent of the Teaching Resource Pack which has been produced for organ donation and transplantation. A further possibility might be the establishment of an education programme with the participation of the Royal College of Pathologists. No matter the form(s) adopted, the Review Group wishes to reinforce the need for adequate education and training in this area to be made widely available.**
- 81 One issue which the sub-group discussed in detail was whether there was a need to include in the forms a section allowing specific authorisation of genetic testing, because of the implications that would have for the present or future health of other members of the family. This reflects concerns about the possibility of genetic information becoming available when either it is not wanted or it might be regarded as confidential. However, such a section has not been included, on the grounds that *any* post-mortem examination has the potential to reveal diseases or conditions with implications for the family, and this would be masked if genetic testing were to be singled out.

Nonetheless, the Review Group recognises that genetic information can be different, and would welcome wider discussion of this point. Where a genetic condition is revealed, the family should of course be offered specialist counselling.

- 82 In this phase of the Review Group's work, we reinforced our view that – where possible – the wishes of the deceased person should be those which are determinative of what happens after death. Although we have used the term 'relative' throughout this report, we repeat our initial attitude that this is only a shorthand for the person most likely to know what the deceased would have wished (in the absence of clear instructions from the deceased). Although this person may well be the closest relative(s), the reality of modern life may mean that this is not so. In order to ensure that the deceased's wishes are prioritised, it is obviously necessary to know what they were. **Thus, we believe that it would be appropriate when a person is admitted to hospital, for them not only to be asked for the name of their next of kin, but also (or instead) that they are invited to nominate a person whom they feel would most accurately be able to speak on their behalf. General Practitioners could also record such information in the patient's records.**
- 83 The Review Group accepts that there is a limit in practice to the extent to which hospitals can be expected to inquire into the intimate details of patients' relationships. For this reason, the adult form allows the person with whom the hospital is dealing to confirm that he or she is not aware of anyone with a nearer relationship to the deceased who ought to be asked to make decisions about a post-mortem examination. Where a patient has not nominated someone as their nearest relative, the Review Group **recommends that the default position should be the hierarchy set out in the Adults with Incapacity (Scotland) Act 2000 and the Mental Health (Care & Treatment) (Scotland) Act 2003. Any consultation on the report should ask specifically for comments on this point.**
- 84 The sub-group had concerns about cases where a local authority had guardianship of a child and might, therefore, under the arrangements proposed, be able to authorise a hospital post-mortem examination on the child. **The Review Group takes the view that local authorities should not give such authorisation without having consulted the parents, and if one or both parents objected, as a general rule the post-mortem examination should not go ahead.**

- 85 It is essential that there should be a single authorisation form in use across Scotland for post-mortem examinations on a child, and a single form for adults. The format proposed by the Review Group allows for the inclusion of local contact details, but otherwise there should be no local variations. Even treating the form as a minimum requirement to which other local provisions could be added is unsatisfactory, since that approach would cast doubt on the validity of a standardised form and there would be no way to assess whether the addition of local information detracted from the basic form, even if inadvertently.
- 86 The Review Group realises, however, that there needs to be local acceptance of the new forms. It therefore **recommends that fully designed versions of both the child and the adult form should be piloted in the first place through focus groups consisting of parent or family support groups, pathologists and all levels of staff from Intensive Care Units. Those who saw and commented on the forms and leaflets included in the ‘Final Report’ should also be consulted, and the material should also be open to public scrutiny on the Review Group’s website. The Executive should make sure that there is a widespread opportunity for the public to comment on the forms. This will mean advertising their availability and, if requested, supplying copies by post, as well as placing them on the Review Group’s website.**
- 87 Consideration also needs to be given, in conjunction with the National Resource Centre for Ethnic Minority Health, to the most effective way of conveying the existence of, and information in, the Information Packs to members of ethnic minority groups. The forms and information leaflets will also be sent to the Campaign for Plain English.

INFORMATION LEAFLETS

- 88 Research has shown that 23% of the population is illiterate and a further 20% have the reading skills of a 5 year old. These statistics had to be borne in mind when drawing up the information leaflets, and adds weight to the value of developing a video for families, as has been done in England. This re-emphasises the need for appropriately trained members of staff to be available at all stages to provide any information and assistance which may be needed.
- 89 In devising the forms and the information leaflets, the sub-group was aware of NHS QIS standards, and the need for its material to be consistent with the detail of the standards.

CHAPTER 3

ISSUES RELATING TO POST-MORTEM EXAMINATIONS INSTRUCTED BY THE PROCURATOR FISCAL

- 90 The Review Group is aware of the important need to distinguish between the hospital and the Fiscal post-mortem examination, as well as to ensure that the two types of examination are treated similarly, so far as issues relating to organ retention are concerned. It is pleased to have had the opportunity to look again at this topic. The Review Group believes that a proper understanding of the Fiscal post-mortem examination system is essential to the restoration of public confidence, which in turn is needed in order to achieve an appropriate number of hospital post-mortem examinations in Scotland.

BACKGROUND

- 91 We indicated in our Preliminary Report (published 6 February 2001) that we had concerns about the confusion in the public mind between hospital and Fiscal post-mortem examinations, and that everything possible should be done to remove that confusion. The Preliminary Report also highlighted the need for improvements in respect of the handling of Fiscal post-mortem examinations, particularly in terms of communications with families. It identified two main areas where there was lack of clarity about the roles of hospital and Fiscal staff. One was communicating with families where a death in hospital might require a Fiscal post-mortem examination. The other was communication between Fiscals and pathologists in respect of retention of organs and tissue.
- 92 The Preliminary Report, therefore, contained a series of recommendations addressed to the Lord Advocate. These were referred formally to him by the then Minister for Health & Community Care on 9 May 2001. The Lord Advocate replied on 13 June 2001, indicating that the recommendations had been considered, and revised guidance would be issued.
- 93 As the Crown Office and Procurator Fiscal Service (COPFS) leaflet for bereaved relatives explains, the Procurator Fiscal has a duty to investigate all sudden, suspicious, accidental, unexpected and unexplained deaths and any deaths occurring in circumstances which give rise to serious public concern. Where a hospital doctor or GP is unable to determine the cause of death, he or she will report the death to the Procurator Fiscal. If the Fiscal decides that a post-mortem examination is necessary to determine the cause and circumstances of death, he or she can instruct the carrying out of that

examination. The authorisation of the relatives is not required. This is one of the key distinguishing factors between the Fiscal post-mortem examination and the hospital post-mortem examination. Fiscal post-mortem examinations are carried out by pathologists acting on the instructions of the Fiscal, regardless of the basis on which they are employed.

- 94 This section of the Review Group's report concentrates on three main issues:
- communications with relatives;
 - the research and educational use of organs and tissue retained at a Fiscal post-mortem examination; and
 - standards for Fiscal post-mortem examinations.

COMMUNICATIONS WITH RELATIVES

- 95 In paragraph 86 of its Preliminary Report, the Review Group noted that the Crown Office was revising the information which should be made available to bereaved relatives about post-mortem examinations instructed by the Procurator Fiscal. COPFS has provided the following update:
- **A new information leaflet has been produced, entitled *Advice for Bereaved Relatives*. It is designed to provide basic, essential information to families in the immediate period following a sudden death. It recognises that, at this stage in bereavement, many relatives do not want to receive detailed information, but that it is important to provide a contact point, so that further information can be sought by those who require it at a time when they are able to deal with the information. The leaflet should be provided to the deceased's family in all cases where the Procurator Fiscal inquires into a death.**
 - **Fiscal Area Offices have been supplied with copies of the leaflet for distribution to local police offices, hospitals, GPs, social work departments and undertakers. When distributing copies to external agencies, Procurators Fiscal will ensure that the purpose of the leaflet and the importance of passing it to bereaved relatives are emphasised. It is recommended that copies of the leaflet should be provided to local bereavement support groups for their information.**
- 96 In paragraph 87 of its Preliminary Report, the Review Group pointed out that when a post-mortem examination is instructed by the Procurator Fiscal, the question of seeking the relatives' authorisation did not arise. However,

this did not diminish the need to make sure that relatives are informed, as fully as is consistent with the Fiscal's role in the administration of justice, of the nature and purpose of the post-mortem examination. Verbal information should always be supplemented by written information which relatives can take away with them. All members of staff involved in informing relatives of post-mortem procedure should possess the skills necessary to conduct sensitive discussions. They should have had appropriate training in Fiscal post-mortem procedures and in dealing with the bereaved, and should have sufficient relevant experience to support this. The role of relatives' support groups in providing such training should be borne in mind, and the physical surroundings in which such discussions take place should be appropriate to the sensitivity of the situation.

97 COPFS have provided the following update in respect of these recommendations:

- **The guidance issued to staff makes clear that it is important to ensure that the deceased's family is kept advised of the progress of the investigation - to the extent that to do so is consistent with the proper conduct of the investigation and also to the extent that it is consistent with the wishes of the family. Further, it is recognised that some grieving relatives will not want to receive detailed explanations of the circumstances of the death nor of the process of its investigation. Procurators Fiscal are reminded that it is essential that such wishes should be respected. They are also advised that it is essential to ensure that the family has a contact point within the Procurator Fiscal's office to approach for further information.**
- **Procurators Fiscal have also been instructed that the family should be notified of the involvement of the Procurator Fiscal, although, if appropriate, such notification may be made via a third party such as a police Family Liaison Officer. In such circumstances, the initial contact will be followed up by written confirmation of the involvement of the Procurator Fiscal, outlining his responsibilities, providing a liaison contact within the Procurator Fiscal's office with a telephone number and giving details of what further contact from the Procurator Fiscal may be expected.**
- **Procurators Fiscal must take steps to ascertain what, if any, contact has been established with the family of the deceased. In particular, it should be clarified whether a police Family Liaison Officer (FLO) has been appointed, and, if so, steps should be**

taken to establish what liaison has already taken place with the family and what information has already been provided.

- In conjunction with the police, reporting physician or reporting agency the Procurator Fiscal should obtain information about the family structure and decide who is to be the most appropriate point of contact. It is pointed out that family relationships are increasingly complex, and therefore consideration should be given as to whether more than one point of contact is necessary (e.g. in cases where the family is fragmented).
- Where a particular family member is identified as the point of contact it is essential that there is clarity as to the role of that person in passing information from the Procurator Fiscal to other family members. For the avoidance of doubt this should be committed to writing, following agreement with the relative.
- It should be established whether the family has any particular immediate needs, e.g. whether there is a need for translation (including Braille translation) and whether there are any religious or cultural rites or requirements to be observed following the death.
- It is important to ensure that a proper record is kept detailing the agreed arrangements, any preliminary discussions leading to the agreement, and the details of communications with the bereaved family. In the aftermath of bereavement, particularly a sudden death, grieving relatives will find it helpful to receive written confirmation of the salient points of any less formal contact. The need for sensitivity in such correspondence cannot be over-emphasised.
- A number of training events have been organised for legal staff including:
 - a seminar on 17 May 2002 dealing with the issue of organ retention;
 - a training day on 9 August 2002, attended by legal, precognition, administrative and VIA staff (see below) covering 'Issues surrounding bereavement' and 'Dealing with the next of kin' and including a representative of SAM;
 - a training day on road traffic deaths in November 2002.
- COPFS now has a dedicated legal member of staff organising and co-ordinating training.

- **A modular training programme for legal staff is being developed and implemented, which will ensure that training on all aspects of deaths investigation is delivered in a structured way to all legal staff as part of their core professional training.**
- **VIA is a dedicated victim information and advice service within the Crown Office and Procurator Fiscal Service. The principal aims of VIA are:**
 - **to provide information to victims, bereaved next of kin and some witnesses about the criminal justice process in general;**
 - **to keep victims and bereaved next of kin informed about the progress of the case that affects them in particular; and**
 - **to advise on and facilitate referral to other agencies for specialist support and counselling as required.**
- **VIA services are available to:**
 - **the next of kin in cases involving deaths which are reported for consideration of criminal proceedings and death cases where a Fatal Accident Inquiry is to be held; and**
 - **the next of kin in all cases where there are likely to be, or it becomes clear after initial investigation that there will be, significant further inquiries, or where, in all the circumstances, it is considered that the assistance of VIA would be appropriate.**

98 In paragraph 88 of its Preliminary Report, the Review Group recommended that the Fiscal should explain to the family the reasons for requiring a post-mortem examination, including which organs will or may be removed and/or retained, as soon as this is known. Where relatives object, the Fiscal should explain clearly why the post-mortem must proceed. When objections are made, the Fiscal needs to be clear whether these are based on religious belief, and, if so, to decide the extent to which those beliefs can be accommodated, given the circumstances of the particular case. If the relatives wish, the Fiscal should be prepared to hold a meeting with them to explain the need for a post-mortem examination. In particular, it is the Fiscal's responsibility to make clear that organs can only be retained after a Fiscal post-mortem examination for the purposes of determining the cause of death and other related matters. Fiscals should make clear to relatives what will be done with these organs once this process is completed and should inform relatives clearly about disposal options, including the possibility of returning the organs to the relatives and delaying funeral arrangements in order to permit the retained organs to be reunited with the body. Where appropriate it should be made clear to relatives that continued retention of organs, blocks and slides may be necessary for legal purposes.

99 COPFS have provided the following update on these recommendations:

- **The guidance issued to Procurators Fiscal states that where a post-mortem examination is instructed the representative(s) of the deceased's family must be notified; the nature and purpose of the post-mortem examination should be explained - again, where to do so is compatible with the proper conduct of the investigation. They are advised that an explanation of the need for post-mortem examination, and of its nature, should be provided - unless there is an indication that the family representative does not wish to receive such information. The level of detail provided will depend on the particular circumstances, including the wishes of the bereaved relatives.**
- **It was not possible to find a universal way to ensure adequate communication, and so it is a matter for the Procurator Fiscal to determine what way is most appropriate. Communication can be made through personal contact, via the police or a funeral director, or with the assistance of the GP, hospital or social work staff. The most appropriate means of contact will depend upon the circumstances of the particular case including any existing relationship between the family and other agencies. However, regardless of the means of communication used, a contact point in the Procurator Fiscal's office must be provided to the family.**
- **Procurators Fiscal are advised that, unless organ retention is thought unlikely (if need be following consultation with the pathologist), it will be appropriate at this stage to make reference to the possibility of organ retention and to establish whether the family wishes to be notified if this proves necessary. Where the family does not want to be kept advised it will be necessary to indicate that if organ retention is required, arrangements will be made for the organ to be disposed of sensitively once the further analysis is completed. Procurators Fiscal are advised that it will be important to commit this to writing and to enable the family to return to the Procurator Fiscal should they wish to review their original decision not to be further consulted.**
- **The guidance states that if retention has not been discussed and then becomes necessary there should be immediate contact with the family to notify them and to discuss the options for disposal.**
- **Procurators Fiscal should be aware at an early stage of any religious or cultural issues associated with the death, and they are instructed that if the family has concerns or objections regarding**

the post-mortem examination, consideration should be given to accommodating their wishes, if to do so is consistent with a proper investigation. Careful consideration will be given as to whether, and to what extent, those beliefs can be accommodated without compromising the investigation or a future prosecution. The guidance provides that in appropriate cases it may be necessary to discuss the options with the pathologist and to explain the position of the deceased's family. In the face of sustained objection it may be appropriate to offer a meeting with a representative of the family (or representatives if there are separate interests within the family) to explain the need for an post-mortem examination.

- The guidance provides that Procurators Fiscal must ensure that the options for disposal of organs have been explained to the deceased's family. Again, it may be appropriate to do so through personal contact, via the police or a funeral director or with the assistance of the GP, hospital or social work staff. However, it is recognised that it is important to ensure that the deceased's family is advised of such matters as soon as possible so that consideration can be given to the funeral arrangements. Procurators Fiscal are reminded that such matters will be of profound concern, perhaps particularly to all religious and ethnic groups, and delay in providing information is likely to add to the distress of the bereaved family. A written note should be kept of the family's decision regarding disposal.**

100 In paragraph 89 of its Preliminary Report, the Review Group noted that Regional Fiscals already have a role in auditing the practices of individual Fiscals, and indicated that it would consider it to be an inherent part of that responsibility that the provision of information to relatives should be standardised and included in this audit. In addition, we re-iterated our commendation of the involvement of the pathologists, as in Glasgow, in meeting with relatives and assisting in the explanation of procedures and process.

101 COPFS have pointed out that:

- The guidance commends the Glasgow practice of offering pathology clinics, and Procurators Fiscal are asked to use their discretion and may offer such a meeting to any next of kin where it is felt it would be of benefit. They are advised that such a meeting should be held at the conclusion of the investigation, and**

represents a useful forum to ascertain whether there is a wish for a Fatal Accident Inquiry, and to allay any concerns harboured by relatives about any medical aspects of the death. For a period of perhaps several years it was practice at Glasgow Fiscal's Office to invite the relatives of those who had died of drugs-related death to a meeting with the Procurator Fiscal and the pathologist. Thus an afternoon would be set aside to meet with four or five sets of relatives, resulting in the term 'clinics'. Approximately 4 years ago this practice was reviewed. The view was taken that a meeting with the pathologist should not only be offered in relation to drugs deaths, but should also be available to families in other cases. The need for such a meeting should be determined on the basis of the circumstances of the case and the needs of individual families.

- Currently, the majority of the enquiries from relatives are dealt with directly by the Fiscals at the Deaths Unit. The Fiscal has the experience to deal with the questions that most frequently arise in connection with an post-mortem examination report and can clarify any specific issues with the pathologist. If a death is unusual or complex, and/or where the family indicates that it would be of benefit, then a meeting is arranged. Thus, rather than applying a blanket approach to a particular category of death, the practice is targeted to specific cases where it is of most benefit and is therefore potentially available to all.
- Guidance to Procurators Fiscal refers specifically to the Review Group's view and commends this as good practice to the Service as a whole.
- The structure of COPFS has changed in respect that instead of 6 Regional offices there are now 11 Area offices. Each Area Fiscal had managerial and operational responsibility for their area and each provides the same auditing role.

102 The Review Group notes these changes, and understands the need for some degree of flexibility. However, it also **recommends that this situation is closely monitored and audited**. We return to this at paragraph 108.

103 In paragraph 90 of its Preliminary Report, the Review Group drew attention to the fact that one of the main lessons to be learned from past practice was that there is clearly a communication gap, which needs to be closed, at the point when the Fiscal decides that organs retained at post-mortem examination are no longer required for his/her purposes. The Review Group, therefore, felt that a system needed to be put in place to ensure both that Procurators

Fiscal are notified explicitly and promptly where organs are retained and that the Procurator Fiscal in turn makes sure that the pathologist in possession of the organs is made aware when retention for the Fiscal's purposes is no longer necessary. Appropriate arrangements need to be made to ensure that disposal of the organs then takes place in accordance with the wishes of the next of kin. The Procurator Fiscal should ensure that systems are in place to obtain such information from them.

104 The COPFS response is that:

- **Procurators Fiscal have been instructed to put liaison arrangements in place with pathology service providers to ensure that the Procurator Fiscal is notified, in writing, as soon as the analysis of any retained material has been completed. Guidance states that it may be useful to ask the pathologist for an estimate of the length of time required to complete the analysis and to diarise the case, to ensure the matter is not overlooked. Thereafter, the Procurator Fiscal should confirm to the pathologist that the material is no longer required for the purposes of the investigation, and authorise its release or continued retention, as appropriate, again in writing.**

105 In paragraph 91 of its Preliminary Report, the Review Group suggested that two key steps needed to be taken to avoid any blurring of the distinction between hospital and Fiscal post-mortem examinations. Where the post-mortem examination has been instructed by the Fiscal in respect of a child, and it is conducted in a hospital paediatric pathology department, the Fiscal must take particular pains to make relatives aware of the fact that s/he has instructed the post-mortem and that it is being conducted by a pathologist retained by the Crown Office. Where hospital staff find themselves in the position of having to explain to relatives that a Fiscal post-mortem examination has been instructed, the Fiscal needs to provide a form of words which the hospital staff can use to give the relatives an initial explanation which does not interfere with the proper discharge of the Fiscal's responsibilities.

106 The COPFS response is:

- **Guidance issued to Procurators Fiscal instructs that where an post-mortem examination is instructed in relation to the death of a child, as it will generally be appropriate to instruct both a paediatric pathologist and a forensic pathologist, often it will be appropriate to make use of hospital paediatric pathology facilities. In such circumstances, Procurators Fiscal are advised that it is important to avoid any confusion regarding the nature of the post-mortem examination and to avoid creating the impression**

that a ‘hospital post-mortem examination’ has proceeded without the necessary authorisation from the next-of-kin. It is important to ensure that the parents are aware that the post-mortem examination has been instructed by the Procurator Fiscal and thus that the issue of authorisation does not arise. The guidance issued to Procurators Fiscal states that the death of a child must be reported where: a new-born child is found; where the death appears to have been due to suffocation or overlaying; where the death appears to have been due to SIDS; or, where a child is in foster care, within the care of the local authority or on an ‘at risk’ register.

- **Hospitals are to be provided with copies of the COPFS information leaflet, which should assist medical staff in explaining the Procurator Fiscal’s role.**

107 The Review Group welcomes the work which the COPFS has undertaken as a result of its recommendations. There are, however, a number of matters which it considers require further attention, and these are dealt with in the following paragraphs.

108 The Review Group remains firmly of the view that communication with those closest to the deceased should be every bit as sensitive in Fiscal cases as it is intended it should be in relation to hospital post-mortem examinations. As we have already said, in this report, we have used expressions such as ‘family’, ‘relatives’ and ‘next-of-kin’. However, these are a form of shorthand, and should not be taken literally. They should be understood as also including, in appropriate cases, those who were closest in life to the deceased and who are most affected by the death. This approach is reflected in COPFS guidance and procedures. Guidance to Procurators Fiscal also notes that in some cases this will mean communicating with more than person. The Review Group notes the detailed guidance that has been provided to Procurators Fiscal on the issues raised in the earlier report, but reiterates that it is important to ensure that the guidance is followed routinely and that there is consistency of approach so far as possible across the country. **The Review Group, therefore, recommends that the COPFS should some time in the next 12–18 months arrange for an audit of the effectiveness of the arrangements it has now put in place. This could possibly be done through independent research. Whatever methodology is adopted, the views of families, as users of the service, must be canvassed.**

- 109** The Review Group recommends that there should be a designated person in each area Fiscal's office with responsibility for dealing with families, along the model of the death unit co-ordinator in Edinburgh. This person would be able to ensure that the final diagnosis was communicated to the family, whether or not the diagnosis had changed, and would be responsible for finding out the family's wishes regarding ultimate disposal of any retained organs. In discussing disposal, they should bear in mind that retention may be an option.
- 110** The Review Group notes that the size of Fiscal Area Offices varies, and that some of the smaller offices may find it difficult to adopt the death unit co-ordinator model. It would therefore accept that the smaller offices may need to collaborate in order to provide such an arrangement. **The essential thing from the Review Group's perspective is that the model, or a variant of it, should cover every Fiscal office across Scotland. It notes that there may be a role for VIA here.**
- 111** The Review Group re-iterates its recommendation (paragraph 87 of its Preliminary Report) as to the importance of training, and the potential role of relatives' support groups in providing that training. COPFS already involves some of these groups in training events. The Review Group considers this to be good practice, and **recommends that COPFS should be willing to expand the range of groups involved in such work in future.**
- 112** The Review Group considers that training is also important for medical professionals, including doctors who certify deaths and those who carry out post-mortem examinations. The General Medical Council's pamphlet *The New Doctor* indicates in its section 'Professional Training' that one of the topics which must be covered through in-service training is:
- (h) The duties of doctors under the law:
 - death certification;
 - dealing with coroner/Procurator Fiscal;
 - procedures for cremation;
 - statutory notifications.'

The Review Group **recommends that in taking forward his work with the Deans of Medical Schools, the CMO should pay particular attention to whether or not such training is indeed available, and its quality. Any Medical Schools not offering such training should be reminded of its importance, and required to ensure its availability.**

- 113** The Review Group also considered whether relatives should have a statutory right of appeal against the decision to refer a case to the Fiscal, as well as against the instruction of a post-mortem examination by the Fiscal. In relation to a right of appeal against a decision to refer a case to the Fiscal, the Review Group had concerns about the delay this would cause, and also was worried about the fact that relatives with a criminal interest could be expected to object strongly to a post-mortem examination. It notes that instructions to Procurators Fiscal include a requirement to accommodate the families' wishes, concerns and religious and cultural beliefs where possible in making decisions about post-mortem examinations. On balance, therefore, it does not recommend that a statutory right of appeal against the decision to refer to the Procurator Fiscal should be created. The Review Group prefers an approach based on more informal methods of representation by relatives to the Fiscal, coupled with these instructions.
- 114** In relation to the creation of a statutory right of appeal against a Fiscal's decision to instruct a post-mortem examination, the Review Group is aware that certain states in Australia (Victoria, Western Australia and New South Wales) have legislation which permits formal objection to the carrying out of a medico-legal post-mortem examination.
- 115** The Review Group was not, however, aware of any evidence to suggest that would commend the creation of such a right of appeal in Scotland. As we have already noted, the guidance issued to Fiscals covers the question of dealing with relatives' concerns and taking them into account as far as possible, as well as explaining the purpose of a Fiscal post-mortem examination and the role of the Fiscal in the investigation of deaths. Additionally, we understand that there are some concerns in Australia about the delays which result from this right of appeal. These can compromise the outcome of the post-mortem examination, especially of a baby. The Review Group therefore does not recommend the creation of such a right of appeal.
- 116** The Review Group notes that it may not always be necessary to carry out a full post-mortem examination, involving dissection, in order for pathologists to issue a death certificate. The procedure, known as 'view and grant', involves an external examination of the deceased's body and a consideration of medical notes. In some natural cause deaths, pathologists are able to issue certificates following such examination. This avoids, from the relatives' perspective, the distress that might be occasioned by a full post-mortem examination and the Review Group is attracted to this. The Group is aware that practice in this area varies among pathologists and across the country. It also understands that the assessment of what is required in a post-mortem examination is a matter for the professional judgement and expertise of pathologists, but believes that pathologists should be reminded of this possibility.

- 117 A COPFS-led consultative forum in the Spring of 2003 led to the production of a discussion paper which recommends, inter alia, that a Scottish Advisory Committee for Forensic Pathology (SACFP) be established to oversee the provision of forensic pathology services in Scotland; establish best practice for the speciality; and encourage the development of the profession through the training of practitioners. The paper further recommends that SACFP should set up committees to develop systems for training, accreditation and standards.
- 118 The Review Group would support this recommendation and further **recommends that SACFP, or another appropriately constituted body, should consider the practice of ‘view and grant’ post-mortem examinations and develop standards and guidance for its use by appropriately qualified pathologists. The Group recognises that there may be an educational and training role for relevant professional bodies such as the Royal College of Pathologists and the British Association of Forensic Medicine.**
- 119 The Review Group believes that some further improvements can be made to the information about organ retention and disposal contained in the COPFS leaflet for relatives. The COPFS leaflet, *Advice for bereaved relatives*, discusses the possibility of retention of organs, tissue blocks and slides at post-mortem examination and the options available to the family for disposal once diagnosis is complete. This is supplemented by instructions to Procurators Fiscal to communicate directly with families in cases where organs do require to be retained for diagnostic purposes, to explain this and discuss how they wish to deal with disposal of retained organs once diagnosis is complete. The Review Group commends this approach, which is intended to promote an appropriate and supportive approach, but it has heard some anecdotal concerns about the way in which this communication is handled from time to time. The Review Group has noted that the information on the possibility of organ retention for diagnostic purposes is not replicated in the more detailed leaflet produced by COPFS – *What happens when a death is reported to the Procurator Fiscal* – and is concerned that there is potentially scope for confusion here. **The Review Group recommends that steps should be taken at the first opportunity to ensure that any such confusion is removed. The Review Group notes that the relevant leaflet is under review and recommends that steps are taken by COPFS to include more information on the possibility of organ retention and the options open to the family for disposal of organs once these are no longer required for diagnostic purposes.**

120 The coming into operation on 27 June 2003 of the Cremation (Scotland) Amendment Regulations 2003 will put beyond doubt the ability to have body parts cremated. **This should be taken account of in COPFS information leaflets.** The option of educational, audit or research use of organs, tissue blocks and slides is dealt with in the next section of this chapter.

121 The Review Group is aware that, in homicide cases where criminal proceedings have commenced, the defence may wish to arrange for its own post-mortem examination to take place. This will inevitably delay the release of the body to the family. It is also technically possible, although the Review Group is not aware of any instances where this has occurred, that the defence pathologist would wish to retain material for further analysis. The consent of the Procurator Fiscal to any such retention would be required. **The Review Group considers it to be important that, where relevant, families are advised of the defence post-mortem procedure. It is also vital that, in the unlikely event that tissues/organs are retained in these circumstances, similar procedures in relation to informing the family and arranging for disposal will be applied. Overall responsibility for what happens to a body once the Fiscal has instructed a post-mortem examination rests with the Fiscal, who has control of the body until s/he formally releases it. Any material required for the defence post-mortem examination remains subject to that control.** The Review Group has been advised that the COPFS leaflets are under review and that a dedicated leaflet for families where criminal proceedings or a fatal accident inquiry take place is under preparation. **The Review Group therefore recommends that information about the potential impact of a defence post-mortem examination is included in future versions of the material which COPFS makes available to relatives.**

DEATHS IN HOSPITAL WHERE THE ROLE OF HOSPITAL AND FISCAL STAFF IN RELATION TO COMMUNICATION WITH RELATIVES REQUIRES CLARIFICATION

122 Deaths in hospital which should be reported to the Fiscal include:

- deaths which were unexpected having regard to the clinical condition of the deceased;
- deaths which are clinically unexplained;
- deaths which appear to be attributable to a therapeutic or diagnostic hazard;
- deaths which are apparently associated with a lack of medical care;
- deaths which occur during the administration of a general or local anaesthetic;

- deaths which may be due to anaesthetic procedures; and
- deaths caused by the withdrawal of life sustaining treatment (assisted nutrition and hydration) from patients in a permanent vegetative state.

123 Deaths which could be the result of a medical mishap raise specific issues about communication with relatives. The doctor who is potentially at fault in respect of this death will naturally be cautious about what information he or she gives to the family, and may not be the appropriate person to discuss matters with them. As a matter of course, no-one from the Fiscal's office will be on hand in the hospital. Clearly, someone needs to be on hand to speak to the relatives after such a death in hospital. The Review Group's Preliminary Report (paragraph 82, second bullet point) suggested that consideration should be given to the creation of the post of Bereavement Officer.

Our further work, and that of NHS Quality Improvement Scotland, has strongly underlined the importance of, and our commitment to, this type of appointment. The duties of the Bereavement Officer should be clearly defined to include this type of forensic case. These responsibilities point to the need for the Bereavement Officer to be essentially independent of the Trust and the Area Fiscal's Office. Until such appointments are made, it is important, once such a death has been reported to the Procurator Fiscal, that there is a clear point of contact in the Fiscal's office to whom the relatives can speak. In the meantime, however, hospitals should give immediate consideration as to who should most appropriately discuss such a case with relatives.

124 The Review Group takes the view that, in addition, there is a need for training of hospital doctors about the deaths that require to be reported to the Procurator Fiscal. Improved awareness and understanding of the Procurator Fiscal's role and the types of death that should be reported may help to reduce the number of cases referred to the Fiscal, since anecdotal evidence suggests that doctors may be referring cases to the Fiscal unnecessarily. This emphasises the need for further education of hospital staff about the Fiscal's role in the investigation of deaths, and exposes a further educational/training need. **The attention of hospital staff should be drawn to the COPFS leaflet, *Death and the Procurator Fiscal*, which is designed to give doctors guidance in this area.** The Review Group notes that this publication is under review and recommends that once that process is complete it is re-issued and publicised among medical professionals.

- 125 In relation to the Review Group's original recommendation (paragraph 72 of the Preliminary Report) regarding the need to audit all cases where doctors think a post-mortem examination might be required, **the reasons and basis for referring a death to the Fiscal should be recorded by the hospital. This will allow a proper audit to be carried out which can identify any inconsistent patterns in referral practice, both within and between hospitals.**
- 126 Some cases, for example, those where the person has been in hospital for a period such as a week and then dies unexpectedly, may raise a medical education issue in respect of the process of death certification. The Review Group in its Preliminary Report recommended firmly that responsibility for considering the need for referral to the Fiscal should lie with the consultant and not a junior doctor, which should reduce the number of cases in which it was felt necessary to make such contact. The consultant should also take account of the relatives' wishes where the death was clearly natural, in order to avoid causing them further distress. **We repeat our commitment to each of these recommendations.**
- 127 It is important that, where information is known about the deceased's attitude towards post-mortem examination, or where it is feasible to make inquiries on the subject, that information should be passed to the Fiscal's office, especially where the information relates to religious views. **Each Trust should therefore liaise with its local Fiscal's office to ensure that procedures are in place for the communication of information about the deceased's attitude to post-mortem examination, where these have been voiced or can be discovered. This information, and details of its transfer to the Fiscal, should be recorded in the patient's medical notes. The police may also have such information, and should always include it in any report to the Fiscal.**
- 128 In this context it will be important to bear in mind what is acceptable to the relevant Registrar of Births, Marriages and Deaths in terms of what appears on the death certificate. There needs to be agreed guidelines on the writing of the death certificate. There should, therefore, be further discussion with the Registrar General's Office about the requirements for certification purposes, although the Review Group is aware that the whole process of death certification will be affected by the Report of the Shipman Inquiry.
- 129 The Discussion Paper on Pathology Services suggests (paragraph 6.2) that the Scottish Executive Health Department should consider 'whether mechanisms could be devised for the certification of natural causes deaths that do not require investigation by the Procurator Fiscal, in particular

having regard to the discussion around availability of an independent medical intermediary to assist doctors in certifying such deaths and mechanisms to facilitate the conduct of hospital post-mortem examinations in such cases'. The Review Group understands that a working group is being set up by the Scottish Executive Health Department to prepare a consultation paper on a general modernisation of burial and cremation legislation, and that the remit of that working group will take account of recent developments in England and across the UK in respect of death certification (in particular *Death Certification: the report of a fundamental review* and *Shipman III - Death Certification and investigation of deaths by coroners*). **The Review Group would expect that working group to take account of its concerns about death certification, as well as the points made in the Discussion Paper on Pathology Services.**

- 130** Consideration of this category of case reinforces the Review Group's original proposition that they should be handled at consultant level, and that further medical education and training are needed in relation to death certification and the post-mortem examination processes. The Review Group is aware that the Chief Medical Officer has already put in hand work with the Deans of the Medical Schools and Trust Medical Directors in order to take this work forward (paragraph 33). **The nature of this work must be clarified and publicised, and its implementation speeded up. In any event, consultants should be encouraged to contact the Fiscal if they are concerned about any particular case, rather than simply assuming that it must be referred to the Fiscal.** This further underlines the need for greater awareness of the list of cases which *must* be referred to the Fiscal, and those where discretion may be exercised.
- 131** Overall, the issues raised in this section point to the need for closer liaison between, and training, of doctors and Fiscals as a way of avoiding the problems of the past. **The Review Group recommends that the Health Department and COPFS, in conjunction with the Royal Colleges and NHS Education for Scotland, should consider organising joint seminars on a regular basis to promote mutual understanding of medico-legal post-mortem examinations.**

RETENTION AND USE OF TISSUES AND ORGANS FOR EDUCATION AND RESEARCH FOLLOWING A FISCAL'S POST-MORTEM EXAMINATION

- 132** One of the main lessons from past post-mortem examination practice is that there needs to be complete clarity about the purpose for which material is being retained from a Fiscal's post-mortem examination. First and foremost, retention will be for the Fiscal's purposes in seeking to determine the cause,

mode and related circumstances of the death. There are also reasons for retaining the material where the diagnosis is in doubt, and future tests may be devised which would help to determine the diagnosis. This applies to tissue blocks and slides in Sudden and Unexplained Deaths in Infancy/Sudden Infant Death Syndrome cases (SUDI/SIDS), where the diagnosis is unclear. It may also apply in other cases, such as unsolved criminal cases which may need to be looked at again. There is general agreement on the importance of having access to archived material in this context, but this should properly be regarded as a matter of future diagnosis rather than research. No authorisation is, therefore, required from relatives in respect of retention for these purposes.

- 133** The Review Group understands that it is current practice for tissue blocks and slides to be retained routinely following such post-mortem examinations. It is uncertain of the present basis for such retention, in cases other than those mentioned in the previous paragraph, once the Fiscal's examination has been completed, since no authorisation to do so has been given by the relatives. The Review Group, however, recognises the undoubted potential value of retaining such material as part of the medical record, for research, audit of forensic practice or educational purposes. It therefore considered how such practice could be placed on a proper footing, consistent with its overall approach to the retention of organs and tissue.
- 134** One approach would be to include a provision in the proposed legislation which would deem such tissue blocks and slides to be part of the medical record. They would then automatically become available for use for purposes such as research, medical education, training and audit. Such an approach might be seen to put at a disadvantage the families of those who had been the subject of a Fiscal post-mortem examination, as there would be no place in such a system for families to have control over any part of the process. The tissue blocks and slides would have been prepared without the families' authorisation, and their use for purposes other than the Fiscal's would have no reference to the families' wishes. That would be inconsistent with the whole basis of the Review Group's approach. In particular, families would not be placed in a position equivalent to those who have authorised the use of tissue blocks and slides following a hospital post-mortem examination.
- 135** The Review Group therefore **takes the view that families should be given the opportunity to authorise the wider use of retained tissue blocks and slides derived from a Fiscal post-mortem examination, in the same way, and for the same purposes, as can be authorised following a hospital post-mortem examination.**

- 136 In making this recommendation, the Review Group acknowledges the need for clarity about the process involved. Tissue blocks and slides will automatically be created as the end-product of a properly-conducted post-mortem examination performed on the instructions of the Fiscal. If these are to be retained further for the Fiscal's purposes, no authorisation from the families is required, as we have already noted at paragraph 132. **Once the Fiscal's purposes are complete, however, we consider that the blocks and slides should be regarded as part of the deceased's medical record, since they complete his or her medical history.** What must be clearly understood, though, is that in the case of the Fiscal post-mortem examination, a separate authorisation of the use of the blocks and slides is required, since the family will have had no opportunity to consider and authorise their retention or use. That is the basis on which we have devised the authorisation forms for use in the Fiscal context. Only once the form has been completed giving authorisation can the blocks and slides be used for purposes such as medical education, training, audit and research.
- 137 **The Review Group is also clear that no wider use of any retained organs is permissible unless the deceased had or the family has specifically authorised this, irrespective of the nature of the post-mortem examination.** The Isaacs Report indicated that, in the past, arrangements existed which allowed brains (and other organs) to be retained from coroners' autopsies in England and Wales for research purposes without the relatives knowing about this, let alone being asked for consent or authorisation. The Review Group reiterates its position that such practice is unacceptable. Arrangements are now clearly in place to prevent this happening in Scotland but the Isaacs Report further underlines their importance.
- 138 The Review Group noted in its Preliminary Report that even those families most traumatised by the revelations about organ retention - and the majority of representations received by the Review Group from relatives about post-mortem practice related to Fiscal cases (paragraph 56 of Preliminary Report) - maintained their support for medical research. This was based not just on the benefits they themselves might obtain in terms of future reproductive and other choices, but also in recognition of the wider benefits to society which could result. That support has been embodied in the arrangements introduced with effect from 18 October 2002 allowing research to be undertaken, subject to certain conditions, on archived tissue obtained under past post-mortem examination practice. The arrangements apply equally to material obtained from hospital or Fiscal post-mortem examinations.
- 139 The importance of research following Fiscal post-mortem examination cases is beyond doubt. In many of them, further investigation could lead to a

clearer understanding of the disease from which the patient died, and to the development of better diagnostic methods. For example, examination of the brain in HIV-infected drug users who have died suddenly has often revealed the presence of unsuspected severe brain disease.

- 140** In putting in place a mechanism which would allow relatives to authorise the use, for educational and/or research purposes, of organs, tissue blocks and slides retained originally for the Fiscal's purposes but no longer required for them, the Review Group is anxious to ensure that this mechanism should operate so as to cause as little additional distress to relatives as possible. The Review Group is also aware that such arrangements require clear communication between Fiscal offices and pathologists to establish when material is no longer needed for the Fiscal's purposes. In addition, the wider public interest in the research importance of this material should not be compromised by the very process of seeking authorisation. The mechanism must be as clear and simple as possible.
- 141** The Review Group notes that there are two distinct situations in which authorisation for the research, educational or other legitimate use of material derived from a post-mortem examination will need to be sought. First, in deaths from certain causes, into whose pathology an existing research project is under way (for example in relation to CJD), it may be desirable that material additional to that which is strictly necessary for the purposes of the post-mortem examination itself is also removed and retained. In this situation, authorisation will need to be sought before the post-mortem examination takes place. Second, it may be regarded as important that material removed at post-mortem be retained for research, education or audit. More commonly, authorisation for this will be sought after the examination, at the point at which the Fiscal has completed his or her investigation. A specific form for this authorisation in both sets of circumstances is included in Appendix 3, in both adult and child versions. They are consistent with the hospital post-mortem examination authorisation forms.
- 142** **In either situation, when retention for research or other purposes is desired, a suitable authorisation form must be given to the relatives which they should be invited to consider. They should also be given an information leaflet which explains the purposes of the removal, retention or use, and which supplements any verbal explanation provided as part of the process of seeking authorisation.**
- 143** The Review Group gave considerable thought as to who should take responsibility for seeking authorisation for research or other purposes, and providing information for relatives, in a way which does not disrupt Fiscal

practice. It is not a duty which Fiscal staff should be expected to perform, but they need to be aware of the possibility of authorisation, and information about this should be included in COPFS leaflets for relatives. Ideally, the responsibility for seeking authorisation should rest with the bereavement officers whose appointment we have already recommended (paragraph 123). Until then, it is not clear who should have this responsibility. It could be argued that those best placed to seek authorisation are the researchers themselves, but this raises a number of practical issues. In the normal course of events, University forensic departments have no point of contact with families, and the introduction of a new person could in itself cause families additional distress. Families will, however, have already had contact with a police administration officer or mortuary technicians, who are skilled in dealing with bereaved families. It might therefore best be left to each institution or department to establish the most appropriate person to fulfil this task. There is also the question of where and how the authorisation form is to be completed. Options would be for the person seeking authorisation to visit the family, or to arrange a meeting elsewhere, or to contact the family to find out if it would be acceptable to post the form to them, supplemented by communication with the contact person, or a pathologist if required. Each of these approaches has drawbacks, so, given the importance of this work to families and society as a whole, **we recommend that views should be sought on these practicalities, with the aim of finding the approach which best meets the needs of research without causing families unnecessary additional distress.**

144 The Review Group recommends that the research and education authorisation forms and information leaflets included in Appendix 3 should be adopted for use across the country as a whole.

145 A potential conflict arises in relation to post-mortem examinations where relatives may be under suspicion of being implicated in the death. For instance, there is an urgent need for research in cases such as non-accidental injury in children, but there are likely to be constraints on approaching relatives for authorisation in such circumstances. These complications need not prevent relatives' authorisation being sought for research after Fiscal post-mortem examinations where no such suspicion exists. But in cases where the person who would give authorisation is under suspicion in respect of a death which is thought to be criminal or unnatural, there may be circumstances in which the interests of justice should perhaps allow research to take place without specific authority. As this runs counter to the Review Group's general commitment to the rights of families, **we recommend that there should be consultation on this point.**

STANDARDS FOR FISCAL POST-MORTEM EXAMINATIONS

146 Another main recommendation in the Review Group's Preliminary Report was that the Clinical Standards Board for Scotland should include amongst its generic standards one relating to the conduct of the post-mortem examination (recommendation q). We accept that professional standards are matters for the relevant medical bodies, and we have already recommended that training and education of medical personnel in this area should be reviewed. However, in terms of our remit, the standards to which we refer are those which relate to the operational manner in which such procedures are carried out. Standards of this sort were published by NHS Quality Improvement Scotland, within which the Clinical Standards Board was subsumed on 1 January 2003. When the Board (as it then was) considered that recommendation, it came to the conclusion that there was a need for a separate set of standards relating to Fiscal post-mortem examinations.

147 The section of the NHS QIS report dealing with Overarching Principles makes the following point:

While the standards only apply to NHS services, the Project Group recognise that most post-mortem examinations are carried out by the Fiscal service, which is outwith the NHS. No authorisation is required for a Fiscal post-mortem examination, nor for the retention of material, including organs, tissue blocks and glass slides taken for evidential purposes. The standards are therefore highly commended to the Crown Office to be applied when post-mortem examinations are carried out under the jurisdiction of a Procurator Fiscal to establish the cause of death. The members of the Project Group stressed the importance of ensuring that relatives will be given as much information as possible.

148 Concern regarding the lack of quality assurance for medico-legal post-mortem examinations is expressed in many reports, including the Isaacs Report and the Review of Coroners. The lack of quality assurance programmes for Coroner or Fiscal post-mortem examinations means that much evidence regarding poor quality post-mortem examinations is anecdotal or highlighted only in specific cases. The Review of Coroners does highlight the Confidential Enquiries into maternal and post-operative deaths which found 'a significant proportion of [post-mortem reports done for coroners] to be below standard'.

149 A National Sentinel Clinical Audit of Epilepsy-Related Deaths (SUDEP Report) reviewed the quality of the post-mortem examination in these deaths (based on the post-mortem examination reports) all of which had

been undertaken at the instruction of the Coroner or Procurator Fiscal. The pathology panel looked at four aspects of the post-mortem examination: the external examination, internal examination, the further investigations undertaken and the certification of death and broke down the analysis by country. Less than 13% of the post-mortem examinations were considered adequate (England 13%, Scotland 9%, Wales 7%). In Scotland, the problems lay not with the technical aspects of the post-mortem examination (external and internal examinations) which were all satisfactory (in contrast to England where 8% and 31%, respectively were inadequate), but with the extent of the further investigations (36% inadequate) and the certification of death (52% inadequate). Thus, while there may be some reassurance that in Scotland the examination was conducted to comply with RCPATH guidelines, epilepsy deaths are one of the types of death where further investigations are essential and poor certification is always a concern.

- 150** A system of audit for all forensic pathology work must be established. The Review Group noted in its first report that there was a need for fundamental changes in the culture of NHSScotland, particularly in relation to medical education and training in respect of post-mortem examinations and associated issues such as death certification. As indicated earlier in this Report (paragraph 130), **the work which the Chief Medical Officer is undertaking with the Deans of Scotland's Medical Schools and with Medical Directors requires further effort.**
- 151** The development of standards is intended to ensure consistency of approach across the country as a whole to key elements of post-mortem examinations, specifically in respect of communication with relatives. Lack of consistency of approach has been one of the issues which has most troubled the families affected by past post-mortem examination practice, whether in the hospital or Fiscal context.
- 152** The Discussion Paper on Pathology Services noted (paragraph 3.2.12) that there was widespread agreement on the need for objective standards, and that this would be a suitable task for the proposed Scottish Advisory Committee on Forensic Pathology. The Review Group felt that since it might be some time until that Committee could be established, the adaptation of the hospital post-mortem examination standards should be one of the sub-group's main tasks. Its membership deliberately included some of those who had been involved in the preparation of the original standards, and assistance was also provided by NHS Quality Improvement Scotland staff. The suggested Fiscal post-mortem examination standards are set out in Appendix 2.

- 153 This approach is not to be taken as implying that the Fiscal post-mortem examination is simply a variation of the hospital post-mortem examination. Fiscal post-mortem examinations can be divided (at least) into those deriving from the Fiscal's function to investigate sudden or unexpected deaths, and those directed at investigation of criminality. In the latter case, the main concern is the way in which the evidence will stand up in court, and hospital-based standards have little to do with that. These considerations have been borne in mind in producing the standards for Fiscal post-mortem examinations.
- 154 The Review Group takes the view that these standards are a public document, rather than merely protocols for professionals. This means that they require to be self-standing, and should therefore include general material on post-mortem examinations, not just material specific to Fiscal post-mortem examinations. **The draft standards included in this report are commended to the Minister for Health & Community Care, the Lord Advocate and the Minister for Justice to consider how best they can be taken forward, bearing in mind the potential role of the proposed Scottish Advisory Committee on Forensic Pathology.** Whatever mechanism is devised needs to take account of the fact that the standards potential apply to a number of agencies, including COPFS, NHS staff and the police, as well as pathologists providing forensic pathology services to the Crown. **The Review Group recommends that all relevant agencies should be consulted on the draft with a view to producing an agreed set of standards, for which each can feel a sense of ownership.**
- 155 **The Review Group recommends that arrangements should be made to review performance against those standards, taking account of the recommendations of the Review Group.**

OTHER ISSUES

- 156 The Review Group considered the question of whether the list of cases to be reported to the Fiscal should be included in statute. This would make it easier to find them, and would make it easier for medical and other professionals to be aware of those cases which the Fiscal would require to investigate. Such a step would, however, make it much more difficult to take account of unforeseen changes and the emergence of new categories. The Review Group therefore does not recommend that the list should be included in primary legislation, but **recommends that some other way be found to make this information available in the public domain and readily accessible.** The Review Group felt that including the list in Regulations was not only impracticable, given the absence of any regulation-making power, but also unnecessary. **It recommends, however, that views on this point should be canvassed in any consultation on this Report.**

CHAPTER 4

**ETHICAL REVIEW OF RESEARCH PROJECTS
INVOLVING HUMAN TISSUE RETAINED AT
POST-MORTEM EXAMINATION**

- 157** In his announcement of 19 July 2002 setting out his response to the consultation on the Review Group's 'Final Report' (November 2001), the Minister for Health & Community Care indicated that one of the Review Group's specific tasks in Phase 3 would be to consider how best to provide an ethical review of all research projects involving human tissue retained at post-mortem examination, until such time as the legislation was enacted to put research ethics committees on a statutory basis.
- 158** It should be noted at the outset that the Review Group took the view (paragraph 80, 'Final Report') that it would be unproductive to require REC approval before a pathologist could legitimately stain retained slides from his or her previous cases. Although he or she would, strictly speaking, be engaging in research, agreement to post-mortem examination, when expressed in terms of the new authorisation forms developed by the Review Group, entails that tissue blocks and slides become the 'property' of the hospital and form part of the medical record. As authorisation will have been directly obtained for this in both hospital and Fiscal post-mortem examinations, this should present no additional problems and will not therefore be further considered.

**RESEARCH INVOLVING ORGANS OR TISSUE RETAINED FOLLOWING
PAST PRACTICE**

- 159** In relation to new research projects involving human tissue retained under past post-mortem examination practice (both hospital and Fiscal examinations), it has already been agreed that such research can begin 6 months after the formal start of the 5-year period during which families can reclaim organs or tissues retained under past practice. The 6-month period expired on 18 October 2002.
- 160** Two key criteria were devised by the Review Group, in conjunction with family support groups, for deciding whether that research should go ahead. One is that the research has the potential to make a significant contribution to diagnosis or therapy; the other that the research itself will be non-destructive. In general, the term 'non-destructive' is taken to mean that the research should allow some of the material to remain, so that if a family were to become aware that material had been retained, discover that it was being used in a research project, and decide that they did not wish the material to

be used in that research, there would be something left which could be disposed of, either by the family or the hospital (as the family wished). A 'significant' contribution is taken as one which makes, or is likely to make, a real contribution to medical advances in diagnosis or therapy. It should be remembered that these restrictions only apply until the end of the 5-year period on 17 April 2007 to organs or tissue retained under past practice (that is, before the end of the year 2000).

161 Given this, the Review Group does not feel that further elaboration of this recommendation is required. In particular, the Review Group does not consider it necessary to approach individual families to seek their authorisation for the proposed research use of the material. Unless families have expressed a wish that such an approach should be made, it would be an unacceptable intrusion, particularly in cases where the family is unaware that organs and tissues have been retained, and/or has chosen not to find this out. This is consistent with the Review Group's view that, in relation to investigation of past post-mortem practice, the initiative must always rest with the families.

162 Any Research Ethics Committee (REC) which has been asked to approve a research project involving human organs or tissue derived from past post-mortem examination (that is, where no authorisation was obtained from the family or the deceased) should satisfy itself that the project is likely to make a significant contribution to diagnosis or therapy; and that the research is non-destructive. **In order to assist RECs in ascertaining under which practice organs or tissue were retained, Trusts should prepare and make available a statement explaining from what date their local 'consent' forms became effective and made specific reference to research uses of retained organs or tissue.**

163 In such cases, the REC should also satisfy itself:

- that no tissue blocks or slides will be used to prepare additional slides unless research questions cannot be answered using lawfully obtained tissue or organs;
- that the amount of tissue or organ to be used is limited to the minimum amount necessary to enable the research to be carried out; and
- that the material should not be used at all if the outcome of the research is unlikely to yield a reliable or informative result, whether positive or negative.

RESEARCH INVOLVING ORGANS AND TISSUE RETAINED DURING THE PERIOD JANUARY 2001 UNTIL THE INTRODUCTION OF THE NEW ARRANGEMENTS

- 164 The Review Group understands that since the end of 2000, the consent forms used by all Trusts in Scotland contain specific provisions allowing families to agree to the removal, retention and subsequent use of tissue and organs. The specific details of what has been discussed and agreed to should have been accurately and thoroughly recorded. Until the new authorisation forms and arrangements are in place, research can of course proceed, but it must be clear, and provable, that adequate information has been provided (unless this has been refused) and that valid consent has been given. **RECs should require sight of the local form before approving projects, and should assess its quality in light of the recommendations of the Review Group.**
- 165 In this context, ‘consent’ is taken to cover any form of permission which was granted prior to the introduction of the standard authorisation forms for paediatric and adult hospital post-mortem examinations or for the research use of material removed and retained at a Fiscal post-mortem examination which is no longer required for the Fiscal’s purposes.
- 166 Where the research proposal is consistent with the consent provided, the REC must, within the general guidance for RECs, apply pragmatism and common sense to its consideration of the specific proposal. While the goals of any research project should not be permitted to over-ride the dignity, rights, safety and well-being of the family of those whose tissue is being used in the project, questions of balance and public good should be addressed carefully.

RESEARCH INVOLVING ORGANS AND TISSUE RETAINED FOLLOWING INTRODUCTION OF THE NEW FORMS AND REGULATIONS

- 167 The Review Group has now devised standard authorisation forms, both adult and paediatric, which provide for explicit authorisation of the research use of organs retained at hospital post-mortem examination. It has also devised a similar form allowing such authorisation in the case of post-mortem examinations instructed by the Procurator Fiscal, once the Fiscal has indicated that the organs are no longer needed for his/her purposes. Blocks and slides derived from both types of post-mortem examination will, following authorisation, become part of the medical record and therefore available for research without further specific authorisation, unless their retention is for diagnostic purposes, for example in cases of SIDS. Such research must, of course, be carried out within the general framework of ethical approval and confidentiality.

- 168** Once the standard authorisation form has been brought into operation, RECs should require all research applications to contain a copy of this form. They will wish to satisfy themselves that the authorisation is in terms which would permit the relevant material to be included in the project. Where it concludes that the use envisaged by the project is inconsistent with the authorisation, the Committee has no option but to refuse to approve the project, or to permit the project to go ahead without the inclusion of that material.
- 169** The Review Group made clear in its ‘Final Report’ (paragraph 81) that it cannot, and does not, condone the routine removal and retention of organs or tissue for no intended purpose. It accepts that situations may arise where researchers may have no specific project in mind when seeking authorisation for the removal and retention of organs or tissue, but they will nonetheless have to establish protocols for their storage and management which should be of the highest possible standard, and open to public scrutiny. However, in such circumstances removal and retention for research purposes must in any event have been properly authorised, and RECs should ensure that they are satisfied as to the quality of the authorisation. Particular attention should be paid to the possible uses of material archived in any tissue banks, and to the regulations which cover its use. Since any research will still require REC approval, it may in such circumstances be said that the removal and retention of human material is done with the intention of its use for approved research in the future. Thus, retention is for that general purpose and could be authorised by the deceased, the parents or the next of kin.
- 170** In keeping with the Review Group’s general approach, the aim should be to give effect to any views which the deceased might have expressed in life. The expression ‘next of kin’ should be understood in this context as meaning those closest in life to the deceased; that is those who are best placed to be able to say what the deceased’s attitude would have been (as opposed to being invited to express their own views).
- 171** In this context, the REC will need to obtain a declaration from the researchers that the use of the material is consistent with section 3 of the authorisation form, which will contain any conditions or limitations on the use of specific material. It would be unethical to act counter to this authorisation, or to use the material for unwanted inquiries. Researchers have a duty to ensure that any recorded conditions or limitations are respected, which means that they must take precedence over the aims of the research project. In those cases, the Committee’s options are to refuse to approve the project, or allow it to proceed without the relevant material, if that is feasible.

- 172 Where it comes to the attention of a REC that research involving human organs or tissue retained from post-mortem examination is being carried out which it has not been asked to consider, or which it has considered and rejected, the Committee should bring the matter to the attention of its appointing authority, the relevant NHS body and the appropriate professional body. In the latter case, in particular, the REC should bear in mind that a criminal offence may have been committed.

ADDITIONAL CONSIDERATIONS

- 173 It is important for families to be aware of any information which can be made available about the outcomes of particular research projects, whether this is achieved by way of an annual report, a specific publication or in some other way. **Researchers should therefore report back to the REC on completion of the project with any information about the availability of the results.**
- 174 The Review Group notes that the implementation of the EU Directive on Clinical Trials, which makes provision for a single ethical opinion and sets out criteria with which bodies offering an ethical opinion must comply, will in part take forward the recommendations in paragraph 99 in its 'Final Report' (page 60) concerning the structure of RECs. In implementing EU Directives, the UK is the member state, so the regulations implementing the Clinical Trials Directive are laid in the Westminster Parliament on behalf of the UK (the primary legislation is the European Communities Act 1970 (section 2.2)). These regulations propose the establishment of a United Kingdom Ethics Committee Authority (UKECA) as the legal entity through which the UK will discharge its responsibilities. UKECA will effectively consist of the Health Ministers of the 4 countries. The legal duties and powers of UKECA will include the establishment of Research Ethics Committees and the recognition of RECs established by other authorities, e.g. RECs established by NHS Boards.
- 175 Although the Clinical Trials Directive applies only to clinical trials of medicines, the Review Group is informed that NHS RECs are part of the wider governance framework and it is intended to 'recognise' all NHS RECs, which fulfil the accreditation requirements, thus making them legal entities. We anticipate that the majority of RECs will apply to be recognised to review all research being undertaken in the NHS, which is their current remit. It will be up to each committee to decide what it wishes to be recognised for but even if it did not apply to be recognised to review clinical trials it would still be a legal entity. The Review Group awaits the precise

terms of the new arrangements with interest, and reiterates its concerns ('Final Report', paragraph 86, page 56) concerning training and selection of members of such committees. **Changes to the basic structure of these committees provide an ideal opportunity to review membership and training opportunities, and the Review Group reiterates its earlier recommendation that this should be undertaken as a matter of importance.**

APPENDIX 1

MEMBERSHIP OF REVIEW GROUP AND SUB-GROUPS

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1 INTRODUCTION

This document introduces *Standards for the Management of Post-Mortem Examinations Instructed by the Procurator Fiscal*. These standards apply the following areas:

- Pathology Practice - Post-Mortem Examinations
- Communication and Information
- Storage, Handling and Disposal
- Record-Keeping
- Education and Safety

The initial sections of this document provide background information on the Procurator Fiscal's role in the investigation of deaths and the instruction of post-mortem examinations and on the management of Procurator Fiscal post-mortem examinations (Sections 2 and 3 respectively).

The overarching principles underpinning the standards are provided in Section 4.

Section 5 contains the Standards for the Management of Fiscal Post-Mortem Examinations.

Finally, Section 6 provides a glossary of terms used in the standards.

2 BACKGROUND ON THE PROCURATOR FISCAL'S ROLE

The Procurator Fiscal in Scotland has responsibility for the investigation of all sudden, suspicious, accidental, unexplained or unexpected deaths and any death that occurs in circumstances that might give rise to serious public concern. This is separate but related to the Procurator Fiscal's role in connection with investigation and prosecution of crime.

Deaths are usually brought to the attention of Procurators Fiscal in reports from the Police, the Registrar, GPs or hospital doctors. However, anyone who has concerns about the circumstances of a death can report it to the Procurator Fiscal.

There are certain categories of death that a Procurator Fiscal must investigate and that must therefore be reported to the Procurator Fiscal. These are listed at Appendix 2. The Procurator Fiscal may, however, make enquiry into any death brought to his attention.

An essential part of the investigation of death is the determination of the cause of death. In suspicious and accidental cases it is also important to seek to establish the mechanism of death. Part of that process might require a post-mortem examination to be carried out. In cases reported to the Procurator Fiscal it is a matter for him/her to determine whether a post-mortem is required. The Procurator Fiscal can instruct a post-mortem examination where s/he considers that necessary to establish the cause or mechanism of death. The Procurator Fiscal does not require the authorisation of the deceased's family to do this, but will take families views or religious or cultural beliefs into account in determining whether to instruct a post-mortem and in the arrangements made for a post-mortem examination to be carried out.

It can be necessary as part of the post-mortem examination process to retain organs and/or tissues for further examination in order to establish the cause of death. In some cases it may be necessary to retain small amounts of material as evidence in a criminal trial or fatal accident inquiry. The Procurator Fiscal cannot authorise the retention of such material other than for diagnostic or evidential purposes. S/he will liaise with relatives and keep them informed when this is necessary and seek their views on what should happen to the retained material once that process is complete. In particular no organ may be retained for teaching or research purposes without the authorisation of the deceased's next of kin.

3 STANDARDS FOR THE MANAGEMENT OF PROCURATOR FISCAL POST-MORTEM EXAMINATIONS

Format of Standards and Definition of Terminology

All standards follow the same format:

- each standard has a **title**, which summarises the area on which that standard focuses;
- this is followed by the **standard statement**, which explains the level of performance to be achieved;
- the **rationale** section provides the reasons why the standard is considered to be important; and
- the standard statement is expanded in the section headed **criteria**, which states exactly what must be achieved for the standard to be reached.

The standards set are aimed to be **achievable but stretching**. This is reflected in the criteria. Most criteria are **essential**, in that it is expected that they will be met wherever a service is provided. Other criteria are **desirable**, in that they are being met in some parts of the service and demonstrate levels of quality which other providers of a similar service should strive to achieve.

The criteria are numbered for the sole reason of making the document easier to work with. The numbering of the criteria is not a reflection of priority. The distinction between ‘essential’ and ‘desirable’ is the only way in which criteria have been prioritised.

4 OVERARCHING PRINCIPLES – MANAGEMENT OF PROCURATOR FISCAL POST-MORTEM EXAMINATIONS

Background

A review of post-mortem examination practices in Scotland, particularly in relation to organ retention and documentation on consent and guidance, was recommended by the Scottish Executive in response to strong public concern surrounding past practice. The Review Group on the Retention of Organs at Post-Mortem, chaired by Professor Sheila McLean, was established in September 2000 by the Minister for Health and Community Care with the following remit:

To review previous post-mortem examination practice in Scotland, in particular, in relation to organ retention, and current documentation on consent and guidance, taking account of developments across the UK; to develop a Code of Practice for Scotland with particular emphasis on issues of informed consent and the most effective mechanism for keeping that Code of Practice under review; and to clarify current legal issues with a view to making recommendations.

Basic Facts About Post-Mortem Examinations Instructed by the Procurator Fiscal

A post-mortem examination is a detailed examination of a body after death. The examination usually takes the form of an internal examination. The examination is carried out by a pathologist, who is a doctor specialising in the study of disease, or a forensic pathologist, who is a doctor specialising in the study of causes and mechanisms of death by non-natural causes, and trained in this type of examination.

In cases reported to the Procurator Fiscal, post-mortem examinations might be instructed for the following purposes:

1. To ascertain the cause of death.
2. To ascertain the mechanism of death.
3. To obtain evidence as to the cause and mechanism of death where it will be necessary to establish this in a criminal trial or fatal accident inquiry.

Where a post-mortem is instructed by the Procurator Fiscal this is because the examination is necessary to establish the cause of death. It is not necessary for the Procurator Fiscal to obtain the authorisation of relatives to a post-mortem examination but the Procurator Fiscal does have a duty to keep relatives informed.

In cases where the Procurator Fiscal is involved in the investigation of a death, funeral arrangements may take a little longer. After the post-mortem examination, the pathologist will produce a report which is sent to Procurator Fiscal. The Procurator Fiscal will keep relatives informed about the results of the post-mortem examination.

Basic Facts About Organ Retention

In a Fiscal post-mortem examination, organs or small samples of blood or tissue may be removed and retained to ascertain the cause of death, and may sometimes be required as evidence in legal proceedings. Organs, **tissue blocks and slides** cannot be kept for longer than this, or used for other purposes, without authorisation of the next of kin. At present, the Human Tissue Act 1961 governs the post-mortem examination process, but this is expected to change.

1. Standards for the Management of Procurator Fiscal Post-Mortem Examinations

STANDARD 1 - Pathology Practice - Procurator Fiscal Post-Mortem Examinations

STANDARD 2 - Communication and Information

STANDARD 3 - Storage, Handling and Disposal

STANDARD 4 - Record-Keeping

STANDARD 5 - Education and Safety

STANDARDS FOR THE MANAGEMENT OF PROCURATOR FISCAL POST-MORTEM EXAMINATIONS

STANDARD 1 – Pathology Practice – Post-Mortem Examinations

Standard Statement	Rationale	Criteria
<p>Pathology Examination and Reporting</p> <p>1a. Where a post-mortem examination takes place, both the examination and report follow the guidelines for medicolegal post-mortems set by the Royal College of Pathologists (RCPath). The post-mortem examination is carried out as soon as possible after referral to the Procurator Fiscal and the initial and final reports are provided within the timescales specified by the Procurator Fiscal.</p>	<p>There is evidence that post-mortem examinations and reports carried out to RCPath standards result in increased accuracy of diagnoses and reporting of the cause of death.</p> <p>The information in the report must be made available promptly so that the Fiscal can make progress with enquiries.</p>	<p>Essential</p> <p>1a.1 Post-mortem examinations are audited according to the most recent RCPath guidelines.</p> <p>1a.2 Protocols and procedures are in place to ensure accurate identification of the deceased.</p> <p>1a.3 The post-mortem examination is supervised, or carried out, by a pathologist on the specialist register of the General Medical Council (GMC) and, where required by the Fiscal, with expertise in forensic pathology.</p> <p>1a.4 Paediatric and perinatal post-mortem examinations are supervised or carried out by a pathologist trained in this specific field.</p> <p>1a.5 The post-mortem examination is carried out by the pathologist as soon as possible.</p> <p>1a.6 Reports are sent to the Procurator Fiscal within the timescales specified by the Fiscal. Where reports are delayed, e.g. due to toxicology or histology investigations, information about the delay is available.</p> <p>Desirable</p> <p>1a.7 Other consultants who cared for the deceased in life are identified to the pathologist carrying out the post-mortem where this is possible.</p>

STANDARD 2 - Communication and Information

Standard Statement	Rationale	Criteria
<p>Communication</p> <p>2a. There is effective communication between all those involved before and after the post-mortem examination.</p>	<p>Good communication between all those involved, before and after the post-mortem examination, reduces unnecessary delays, anxieties and concerns, and can improve the accuracy and flow of information.</p> <p>In particular, the pathologist requires information on the deceased and the questions that the Fiscal needs answered at post-mortem examination.</p> <p>In particular the family require information so that they are fully aware of why referral to a Fiscal is made and if a post-mortem is required, what is involved and the outcome.</p>	<p>Essential</p> <p>2a.1 The pathologist carrying out the post-mortem examination is provided with a clinical summary and/or a copy of the police report. The pathologist has access to the deceased's medical records, where necessary and where these are available.</p> <p>2a.2 Relatives are offered information about why the Fiscal has requested a post-mortem and what is involved in this and how to contact the Fiscal for further information.</p> <p>2a.3 There is a clear point of contact in the Procurator Fiscal's office to provide information and answer relatives' questions/concerns about the investigation and the post-mortem process.</p> <p>Desirable</p> <p>2a.4 Relatives are given the opportunity in appropriate cases to speak to the pathologist involved in the conduct of the post-mortem examination in order to have a better understanding of the cause and mechanism of death and key information is provided in non medical terms if possible; and a copy of the post-mortem examination report if appropriate.</p>

Phase 3 report of the Independent Review Group on the
Retention of Organs at Post-Mortem

Standard Statement	Rationale	Criteria
<p>Information</p> <p>2c. Information about the post-mortem examination is available and is offered.</p> <p>Information is sought on the wishes of the family about the post-mortem examinations and where these are known, will be taken into consideration when a decision is made although the ultimate decision lies with the Procurator Fiscal.</p>	<p>The use of information leaflets supports the process of requesting and giving information.</p>	<p>Essential</p> <p>2c.1 Information leaflets in use have been developed in consultation with those providing and involved in Fiscal post-mortems.</p> <p>2c.2 Protocols are in place to demonstrate:</p> <ul style="list-style-type: none"> • Evaluation of the information and relatives' experience. <p>2c.3 There is a designated administrator in the area Fiscal Office whose primary function is to be a point of contact for relatives, to ensure completion of all appropriate forms and co-ordinate.</p>

STANDARD 3 – Storage, Handling and Disposal

Standard Statement	Rationale	Criteria
<p>Glass Slides and Tissue Blocks</p> <p>3a. Tissue samples are taken for diagnostic purposes. Once the Fiscal has confirmed that enquiries are completed and that they have no further requirement for this material, all glass slides and tissue blocks taken at post-mortem examination for diagnostic purposes are retained as part of the medical record of the deceased and are stored securely.</p>	<p>The tissue samples retained are chemically treated to allow preservation for initial diagnosis. This tissue is retained as part of the deceased's medical record to allow diagnostic review and further examination which may benefit the deceased's family, and society in general, as medical knowledge advances.</p> <p>Glass slides and tissue blocks should also be retained for the following valuable purposes:</p> <ul style="list-style-type: none"> • to support audit which will improve care; • for teaching and education of health professionals; • for possible legal and evidential purposes; and • for research purposes. 	<p>Essential</p> <p>3a.1 Glass slides are held for a minimum of 10 years.</p> <p>3a.2 Tissue blocks are held for a minimum of 30 years.</p> <p>3a.3 There is a written policy to ensure secure storage.</p> <p>3a.4 There is a written policy covering disposal where a decision is taken not to retain tissue samples.</p> <p>3a.5 A form has been completed authorising the use of the tissue blocks and slides for audit, education and research.</p>

Standard Statement	Rationale	Criteria
<p>Organs</p> <p>3b. Once enquiries are completed, organs which require to be retained for diagnostic purposes are disposed of with the knowledge and instruction of the relatives of the deceased.</p>	<p>Full diagnostic examination of some organ(s) requires a period of preparation and it may not be possible to return the organs to the body before the funeral.</p> <p>To promote public confidence in the post-mortem examination process, relatives need to be informed when organs cannot be returned to the body immediately after post-mortem examination, and have their wishes taken into account when the organs are disposed of.</p>	<p>Essential</p> <p>3b.1 The Procurator Fiscal liaises with the relatives and there is a record of the relatives' wishes.</p> <p>3b.2 Every hospital/forensic pathology department carrying out post-mortem examinations has a written protocol for the storage, handling and disposal of organs.</p> <p>3b.3 The arrangements for disposal of organs are the responsibility of the department carrying out the post-mortem examination, in line with local protocols. Information on these arrangements is recorded in the departmental database. This information is also recorded in the database of the pathology department carrying out the analysis when this differs from the department carrying out the post-mortem examination.</p>
<p>Residual Tissues</p> <p>3c. Once the Fiscal has confirmed that enquiries are completed, and that they have no further requirement for this material, small pieces of residual tissue which are not processed or stored as part of the deceased's medical record are disposed of lawfully.</p>	<p>Samples require to be of a size to allow for processing. This sometimes results in small pieces of tissue remaining after block selection. All material should be accounted for.</p>	<p>Essential</p> <p>3c.1 There is a written policy for the disposal of small pieces of residual tissue which includes recording how, where and when they are disposed of. Relatives are informed of these arrangements, upon request.</p>
<p>Fetuses</p> <p>3d. Any fetus or embryo having pathological examination is disposed of lawfully and in accordance with parents' wishes.</p>	<p>Awareness and respect of all personal, religious and cultural values and beliefs are fundamental values of NHSScotland. Such awareness and respect reduces the risk of causing any additional distress.</p>	<p>Essential</p> <p>3d.1 There is a protocol in place which sets out local arrangements for disposal of fetuses and fetal tissue. Parents may make alternative arrangements if they wish, and these are documented.</p>

Standard Statement	Rationale	Criteria
<p>Transport</p> <p>3e. Relatives and funeral directors are informed if the deceased, or organs taken for diagnosis, need to be moved to another hospital for post-mortem examination.</p> <p>Transport arrangements for the deceased and/or organs are fully documented.</p>	<p>Post-mortem examinations instructed by Procurators Fiscal are very often carried out at public mortuaries, which can in some cases necessitate the movement of the deceased from hospital to the mortuary or to a hospital with facilities for post-mortem examination.</p> <p>It is also sometimes necessary to transport organs to another site as regional centres exist for specialist examination.</p> <p>It is important to keep relatives informed of transport arrangements as this can reduce anxiety and facilitate funeral arrangements.</p>	<p>Essential</p> <p>3e.1 There is a written protocol for the movement of the deceased and organs between sites. This details how these will be moved and by whom. The protocol covers informing relatives and funeral directors.</p> <p>3e.2 There is a system for recording:</p> <ul style="list-style-type: none"> • the organs transported and the reason why; • the sending and receiving centres; • who sent and received the organs and the dates; and • dates when the organs are returned to the referring department.

STANDARD 4 – Record-Keeping

Standard Statement	Rationale	Criteria
<p>4a. Every post-mortem examination is fully documented and the records retained in accordance with the most recent Royal College of Pathologists Guidelines (NB tissue blocks and slides are a part of the medical record). It is the responsibility of the head of the pathology department carrying out the post-mortem examination to ensure that the above information is recorded.</p>	<p>A full audit trail is required for each post-mortem examination to ensure that the service providing the post-mortem can account for the action taken before, during and after post-mortem examination.</p> <p>This is also required so that any enquiry can be dealt with efficiently and accurately.</p>	<p>Essential</p> <p>4a.1 Documentation from each post-mortem examination includes a copy of the following:</p> <ul style="list-style-type: none"> • authorisation form (re audit teaching/research); • clinical summary; and • post-mortem examination report. <p>4a.2 A copy of the following documents are filed in the department carrying out the post-mortem examination:</p> <ul style="list-style-type: none"> • authorisation form (re audit, teaching/research); • clinical summary; and • post-mortem examination report. <p>4a.3 The medical records of the deceased contain a copy of the authorisation form (re audit, teaching/research) and a copy of the post-mortem examination report.</p> <p>4a.4 All samples taken for cytology, histology and all other investigations are detailed in the post-mortem examination report.</p>
<p>Clinical Audit</p> <p>4b. Clinical audit is only carried out on named samples which were initially taken for diagnosis. This practice is subject to the rules of medical confidentiality.</p> <p>These samples can also be used to validate diagnostic tests and improve clinical care.</p>	<p>Clinical audit is a necessary part of medical practice. Quality assurance programmes are essential to the maintenance of standards which cannot be easily measured without access to pathology data. Clinical histories cannot be audited anonymously.</p>	<p>Essential</p> <p>4b.1 There is evidence that material used for clinical audit and quality control has been subject to diagnosis and subsequent report.</p>

STANDARD 5 – Education and Safety

Standard Statement	Rationale	Criteria
<p>Education</p> <p>5a. All medical staff in training in NHS Trusts are instructed in completing the documentation required following death, the reasons for post-mortem examination, and the ethical and medico-legal framework in which deaths occur.</p> <p>5b. Where medical students are taught using material retained from Fiscal post-mortem examinations, authorisation from relatives is required.</p> <p>5c. Where organs are retained for use in teaching, once no longer required for Fiscal purposes, authorisation is obtained. It is made clear to relatives at that time that their authorisation may be withdrawn at any time.</p>	<p>The documents required after a death need to be completed accurately and in a timely manner. Medical staff need to understand all the reasons why a post-mortem examination is performed and when a death needs to be referred to the Procurator Fiscal.</p> <p>Teaching is necessary for clinical education, and post-mortem examinations provide valuable opportunities for learning.</p>	<p>Essential</p> <p>5a.1 There is an induction programme with input from pathologists for all clinical staff dealing with death, which covers:</p> <ul style="list-style-type: none"> • reasons for a post-mortem examination; • the authorisation process; • religious and cultural issues; • issuing death certificates; • cremation regulations; and • deaths that need to be reported to the Procurator Fiscal. <p>5a.2 Further training is available in communication skills and the bereavement process.</p> <p>5b.1 Forms and leaflets are in use to provide information on teaching and to record authorisation.</p> <p>5c.1 Relatives' wishes in relation to the use of organs for teaching are clearly indicated on the authorisation form.</p>

Standard Statement	Rationale	Criteria
<p>Research</p> <p>5d. Once no longer required for Fiscal purposes, organs which have been taken for diagnostic purposes can only be further retained for research if appropriate authorisation is provided. Information about the purpose of any research will be made available to the relatives if requested.</p>	<p>Organs are a valuable resource for research which may advance medical knowledge and benefit society.</p>	<p>Essential</p> <p>5d.1 Information on research is provided for relatives as part of the authorisation process.</p> <p>5d.2 Relatives' wishes in relation to the use of organs for research are clearly indicated on the authorisation form.</p>
<p>Additional Material for Research and Education</p> <p>5e. Additional tissue slides, blocks or organs may be considered valuable for education and research. In this case, authorisation is required and can be withdrawn at any time.</p>	<p>Material derived from post-mortem examinations is an essential part of medical education and provides opportunities for advancing medical knowledge for the future.</p>	<p>Essential</p> <p>5e.1 There is a protocol for obtaining authorisation for research, which includes information about how this material is to be used and stored.</p> <p>5e.2 There is evidence that authorisation has been obtained.</p> <p>5e.3 There are local arrangements in place to provide feedback on the type of research undertaken.</p> <p>5e.4 There is evidence of regular review of teaching stock to avoid excess retention.</p>

Standard Statement	Rationale	Criteria
<p>Safety</p> <p>5f. All staff (including Procurator Fiscal and police) are aware that, after death, a body can still be a potential source of infection, and observe current Advisory Committee for Dangerous Pathogens (ACDP) and Health and Safety Executive (HSE) guidelines.</p> <p>5g. Anatomical Pathology Technicians (APTs) receive training in all aspects of mortuary practice, which includes the educational and research value of a post-mortem examination as well as its diagnostic function and the risk of infection.</p>	<p>All staff in contact with the deceased are potentially at risk of cross-infection and need to be aware of the level of risk involved in viewing and handling the deceased before and after post-mortem examination. Undertakers should be given sufficient information to minimise the risk of infection.</p> <p>APTs assist in the post-mortem examination and need to understand the laws governing the post-mortem examination, including authorisation.</p>	<p>Essential</p> <p>5f.1 All staff involved in handling the deceased before and after a post-mortem examination are aware of current Health and Safety regulations, including control of infection notification procedures.</p> <p>5f.2 Control of infection notification procedures are in place for the deceased (if required).</p> <p>5g.1 APTs are qualified and hold a certificate in anatomical pathology or equivalent, or work under supervision.</p>

6 GLOSSARY OF TERMS

Term	Definition
accreditation	A process, based on a system of external peer review using written standards, designed to assess the quality of an activity, service or organisation.
anatomical pathology technician (APT)	An individual who assists pathologists during post-mortem examinations, which may involve taking part in the autopsy itself, or collecting specimens and taking notes.
assessment	The process of measuring the quality of an activity, service or organisation.
audit	Systematic review of the procedures used for diagnosis, care, treatment, and rehabilitation, examining how associated resources are used and investigating the effect care has on the outcome and quality of life for the patient.
authorisation	The granting of permission. Formerly referred to as ‘consent’. The concept of giving permission, which was introduced by the Scottish Independent Review Group on the Retention of Organs at Post-Mortem, was felt to be more appropriate than consent in this context.
autopsy	Dissection and examination of a body after death in order to determine the cause of death or the presence of disease process.
clinical governance	A framework through which NHS organisations are accountable for both continuously improving the quality of their services, and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish. Management of clinical risk at an organisational level is an important aspect of clinical governance. Clinical risk management recognises that risk can arise at many points in a patient’s journey, and that aspects of how organisations are managed can systematically influence the degree of risk.

Term	Definition
clinical history	Record of medical events and treatments.
clinical service	Service provided by healthcare professionals.
clinical staff	All medical, midwifery and nursing staff who cared for the deceased during life and after death.
clinical summary	Abbreviated medical history presented in a logical manner.
clinician	An expert clinical practitioner who specialises in clinical work as opposed to laboratory-based studies.
college	In the UK, the term college, when used relating to healthcare, as for example in ‘The Royal College of...’, refers to organisations which usually combine an education role with promotion of professional standards.
consent	The granting of permission. Consent is now referred to as authorisation. See authorisation.
control of infection notification procedures	Guidelines for applying good practice in ensuring infection risks are managed.
core data set	The essential information related to a specific medical condition - may include demographic, clinical management and outcome data used for audit and research.
criterion(s)/ criteria(pl)	Provide the more detailed and practical information on how to achieve the standard, and relate to structure, process or outcome factors.
cytology	The study of cells under a microscope.
data source	The source of evidence to demonstrate whether a standard or criterion is being met.
deceased	A formal word for dead.

Term	Definition
desirable (criterion/criteria)	Good practice that is being achieved in some parts of the service and demonstrates levels of quality to which other providers of a similar service should strive.
diagnosis	Identification of an illness or health problem by means of its signs and symptoms. This involves ruling out other illnesses and causal factors for the symptoms.
diagnostic	The process of determining the nature of a disorder by considering signs and symptoms.
DNA – Deoxy-riboneucleic acid	Material in the nucleus (brain of the cell) that codes what that cell will become structurally and functionally.
embryo	The developing organism from human conception.
essential (criterion/criteria)	A criterion that should be met wherever a service is provided.
evaluation	The study of the performance of a service (or element of treatment and care) with the aim of identifying successful and problem areas of activity.
evidence-based	The process of systematically finding, appraising and using current research findings as the basis for clinical decisions.
fetal	Relating to, or resembling a fetus.
fetus	The unborn child before the age of viable life, currently set as 24 weeks in gestation.
fiscal post-mortem examination	Post-mortem examination carried out on the instructions of the Procurator Fiscal.
General Medical Council (GMC)	Governing body for medical practitioners. Website address: www.gmc-uk.org/
generic standards	Standards that apply to most, if not all, clinical services.

Term	Definition
gestation	The period during which a fertilised egg develops into a baby.
glass slide	The glass plate used to carry material (tissue or cells), and placed on the microscope for examination.
GMC	See General Medical Council.
GP	General Practitioner.
guidelines	Statements which help in deciding how to treat particular conditions.
HDL	See Health Department Letter.
health and safety guidelines	Guidelines relating to health and safety issued by the Health and Safety Executive and other relevant bodies.
Health Department Letter (HDL)	Health Department Letter (formerly known as Management Executive Letter - MEL), formal communications from the Scottish Executive Health Department to NHSScotland.
healthcare professional	A person qualified in a health discipline.
histology	The science concerned with the study of the structure, composition and function of tissues under a microscope.
Independent Review Group on Retention of Organs at Post-Mortem	A Review Group under the chairmanship of Professor Sheila McLean was established to 'review previous post-mortem practice in Scotland, in particular, in relation to organ retention and current documentation on consent and guidance, taking account of developments across the UK; to develop a Code of Practice for Scotland with particular emphasis on issues of informed consent and the most effective mechanism for keeping that Code of Practice under review; and to clarify current legal issues with a view to making recommendations'. The Review Group published its report (also known as the 'McLean Report') in 2001. Website address: www.show.scot.nhs.uk/scotorgrev

Term	Definition
Island NHS Board	Island NHS Boards do the work of both NHS Boards and Trusts, in that they have a strategic and operational role. There are three Island NHS Boards, covering Shetland, Orkney and the Western Isles.
limited post-mortem	A post-mortem carried out on only part of the body, as agreed on an authorisation form.
Management Executive Letter (MEL)	Formal communications from the Scottish Executive Health Department to NHSScotland, now known as Health Department Letters (HDLs).
medical confidentiality	The rules which govern limitation of disclosure of a patient's medical information.
medical records	Patient's notes; documentation of care.
medico-legal framework	The structure that supports both medicine and the law in forensic medicine.
MEL	See Management Executive Letter.
microscope	An instrument used to obtain an enlarged image of small objects.
monitoring	The systematic process of collecting information on clinical and non-clinical performance. Monitoring may be intermittent or continuous. It may also be undertaken in relation to specific incidents of concern or to check key performance areas.
mortuary	A special unit where deceased are kept until formal arrangements for post-mortem examination and/or release are made.
multidisciplinary	A multidisciplinary team is a group of people from different disciplines (both healthcare and non-healthcare) who work together to provide care for patients with a particular condition. The composition of multidisciplinary teams will vary according to many factors. These include: the specific condition, the scale of the service being provided, and geographical/socio-economic factors in the local area.

Term	Definition
NHS Board	NHS Boards replaced the separate Board structures of Health Boards and NHS Trusts. The NHS Boards cover the same geographical area as the old Health Boards. The overall purpose of NHS Boards is to ensure the efficient, effective and accountable governance of the local NHS system, and to provide strategic leadership and direction for the system as a whole, focusing on agreed outcomes.
NHSScotland	The National Health Service in Scotland.
neonatal	A term used to describe the first four weeks after birth.
paediatric medicine	The general medicine of childhood.
pathogens	Any agent that can cause disease.
pathological examination	The examination of organs, tissues and cells.
pathologist	Doctor who identifies diseases by studying cells and tissues using a microscope.
patient	A person who is receiving care or medical treatment. A person who is registered with a doctor, dentist, or other healthcare professional, and is treated by him/her when necessary. Sometimes referred to as a user.
PCT	Primary Care Trust. See Trust and Primary Care.
peer review	Review of a service by those with expertise and experience in that service, either as a provider, user or carer, but who are not involved in its provision in the area under review. In the NHS Quality Improvement Scotland approach, all members of a review team are equal.
perinatal autopsy	The post-mortem examination carried out on stillbirths and babies less than four weeks old.
post-mortem	Relating to the period after death, and also a loosely used term for autopsy.

Term	Definition
primary care	The conventional first point of contact between a patient and the NHS. This is the component of care delivered to patients outside hospitals and is typically, though by no means exclusively, delivered through general practices. Primary care services are the most frequently used of all services provided by the NHS. Primary care encompasses a range of family health services provided by family doctors, dentists, pharmacists, optometrists and ophthalmic medical practitioners.
Procurator Fiscal	The Procurator Fiscal has responsibility in Scotland for the investigation of all sudden, suspicious, unexpected or unexplained deaths.
protocol	A policy or strategy which defines appropriate action in specific circumstances. Also covers the adoption, by all staff, of national or local guidelines to meet local requirements in a specified way, resulting in what are known as local protocols.
public health medicine	A speciality of population-based medicine.
quality assurance (QA)	Improving performance and preventing problems through planned and systematic activities including documentation, training and review.
quality assurance manual	Document outlining the methods and procedures to be used in setting standards and reviewing services.
rationale	Scientific/objective reason for taking specific action.
RCPATH	See Royal College of Pathologists.
residual	Remaining or left behind.
Royal College of Pathologists (RCPATH)	The professional and advisory body overseeing education and qualifications of pathologists. Website address: www.rcpath.org/
Scottish Executive Health Department (SEHD)	The Scottish Executive Health Department is responsible for health policy and the administration of NHSScotland. Website address: www.show.scot.nhs.uk/sehd/

Term	Definition
self-assessment	Assessment of performance against standards by individual/clinical team/Trust providing the service to which the standards are related.
Specialist Register of the General Medical Council	Since 1 January 1997, it has been a legal requirement that, in order to take up a consultant post in the NHS, a doctor must be included on the Specialist Register.
specialty	An area of medicine in which professional specialisation is required.
specimen	A sample of tissue.
standard statement	An overall statement of desired performance.
statutory	Enacted by statute; depending on statute for its authority as a statutory provision. Required by law.
stillbirth	The birth of a baby that shows no evidence of life (heartbeat, respiration or independent movement) at any time later than 24 weeks of conception.
sudden infant death syndrome (SIDS)	The sudden, unexpected death of an infant less than 2 years old from an unidentifiable cause.
tissue	Organs contain tissue, collection of cells which give organs their special function. Samples of tissue (typically small slices about a quarter of an inch thick) are usually taken during a post-mortem examination for examination with a microscope.
tissue block	A sample of an organ embedded in paraffin for processing and examination.
tissue sample	A piece of an organ used for pathological examination.
toxicology	The study of poisonous materials and their effects upon living organisms.
Trust	A Trust is an NHS organisation responsible for providing a group of healthcare services for the local population. An acute hospital Trust provides hospital services. A primary care Trust delivers primary care/community health services. Mental health services (both hospital and community based) are now usually provided by primary care Trusts.

APPENDIX 2 Reporting a Death to the Procurator Fiscal

The Procurator Fiscal has a duty to investigate certain deaths. The categories of deaths concerned may change from time to time and you are advised to refer to the booklet *Death and the Procurator Fiscal* and any supplementary guidance issued for fuller details and advice. Generally the Procurator Fiscal will enquire into any sudden, suspicious, accidental, unexpected and unexplained death. However, the Procurator Fiscal may enquire into any death brought to his or her notice if he or she thinks it necessary to do so. In particular, the Procurator Fiscal will want to know from you of any death where the circumstances or evidence suggest that the death may fall into one or more of the following categories.

- Any death due to violent, suspicious or unexplained cause.
- Any death involving fault or neglect on the part of another.
- Possible or suspected suicide.
- Any death resulting from an accident.
- Any death arising out of the use of a vehicle including an aircraft, ship or train.
- Any death by drowning.
- Any death by burning or scalding or as a result of a fire or explosion.
- Certain deaths of children - any death of a newborn child whose body is found, any death from sudden infant death syndrome, any death due to suffocation including overlaying, any death of a foster child.
- Any death at work, whether or not as a result of an accident.
- Any death related to occupation, for example industrial disease or poisoning.
- Any death as a result of abortion or attempted abortion.
- Any death as a result of medical mishap and any death where a complaint is received which suggests that medical treatment or the absence of treatment may have contributed to the death.
- Any death due to poisoning or suspected poisoning, including by prescription or non-prescription drugs, other substances, gas or solvent fumes.
- Any death due to a notifiable infectious disease, or food poisoning.
- Any death in legal custody.
- Any death of a person of residence unknown, who died other than in a house.
- Any death where a doctor has been unable to certify a cause.

APPENDIX 2 Core Data Set Relating to Standard 4

Hospital Database Information

Name of deceased	
Date of birth	
CHI number (medical record number)	
Name, address and telephone of next of kin	
Fiscal or hospital post-mortem examination	
Date of authorisation for hospital post-mortem examination	
Date death form completed	
Post-mortem examination reference numbers	
Other associated pathology number	
Date of preliminary report	
Date final post-mortem examination report	
Date body received by undertakers	
Date information sent to GP	
Record of information given to relatives	
Record of communication of findings to the relatives	
Number of glass slides	
Number of tissue blocks	
Record of organs retained	

Phase 3 report of the Independent Review Group on the
Retention of Organs at Post-Mortem

Relatives' instructions regarding disposal	
Record of transport of organs	
Date organ sent	
Date organ returned	
Date of organ disposal	
Method of organ disposal	
Tissue samples stored for DNA	
Skin/tissue sent for fibroblast culture	
<i>University records shall provide a confidential audit trail back to the clinical record</i>	
<i>University records shall identify receipt, use, dispersal and disposal of any tissue or sample</i>	

Source: Alder Hey Report, recommendations.

Post-mortem Report (Data Set)

General	Perinatal (Additional Data)
Demographic Details	
Name of deceased	Mother's name
Date of birth	Mother's date of birth
Maiden name	
CHI number (medical record number)	
Fiscal or hospital post-mortem examination	
Post-mortem examination reference number	
Requestor	
Source of request	
Date, place of death	
Date, place of examination	
Report	
Record of specific instructions from the Procurator Fiscal or clinicians	
Type of post-mortem - full/limited	
Clinical history	
Macroscopic report	Measurements
Microscopic report	External measurements
Date of preliminary report	Organ weights
Date of final report	
Name of pathologist and those in attendance	

Phase 3 report of the Independent Review Group on the
Retention of Organs at Post-Mortem

General	Perinatal (Additional Data)
Record of retained organs	
List of histology taken	
Record of photographs, X-rays	
List of other specimens (e.g. genetics, microbiology samples, etc.)	
Summary	
Summary of findings	
Clinico-pathological correlation	

Source: *The Bulletin of the Royal College of Pathologists* 1993(84):11-14

Paper copies - Filed

Case Notes	Pathology Department	Relatives
Signed authorisation form	Authorisation form	Authorisation form
Copy of preliminary post-mortem report	Request (clinical history) form	
Copy of final post-mortem examination report	Post-mortem examination report	
Copy of neuropathology report (if applicable)	Copy of neuropathology report (if applicable)	Copy of final report (if requested)
	Any correspondence	

Child

- Form for the authorisation of a hospital post-mortem examination on a child
- Leaflet giving basic information about such a post-mortem examination
- Leaflet giving more detailed information about such a post-mortem examination

Adult

- Form for the authorisation of a hospital post-mortem examination on an adult
- Leaflet giving basic information about such a post-mortem examination
- Leaflet giving more detailed information about such a post-mortem examination
- Professional Guidance

Fiscal Forms

- Authorisation form for medical use of material retained from post-mortem examination instructed by the Procurator Fiscal on an adult
- Information leaflet
- Authorisation form for use of material retained from post-mortem examination instructed by the Procurator Fiscal on a child
- Information leaflet

AUTHORISATION FOR THE HOSPITAL POST-MORTEM EXAMINATION OF A CHILD

This form and the information leaflet that goes with it are:

- to help you understand what is involved in a hospital post-mortem examination; and
- to provide a record for you and for the hospital about what you want to happen to your child's body and organs if you decide to authorise a post-mortem examination.

Please read the accompanying information leaflet very carefully.

The information leaflet you have been given is a short one, giving important general information. There is another information leaflet if you wish to be given more detailed information and you will be asked if you wish to have this leaflet as well. **If there is anything you do not understand, or want to know more about, please ask the hospital staff.**

If you decide to authorise a post-mortem examination, please complete this form in discussion with the hospital staff, and check that all the information on this form is right. If it is, sign your name at the end of the form. The member of hospital staff who has discussed the examination with you will sign the form as well, and give you a copy to keep.

You should take as long as you need to think about whether you wish to authorise a post-mortem examination and what you would want to happen afterwards. Please note: the post-mortem examination may take place later on the same day on which you give your authorisation.

Box for Contact Details

PAGE 1**Section 1A. Authorisation of a full post-mortem examination**

I am the parent/guardian of _____

and I **authorise** the carrying-out of a full post-mortem examination on my child, which involves keeping small tissue samples as blocks and slides and may involve taking photographs, X-rays and scans. These will be kept as part of the medical record and may be used for **medical education, training, audit and research**. [See also section 3.]

OR**Section 1B. Authorisation of a limited post-mortem examination**

I am the parent/guardian of _____

and I **authorise** the carrying-out of a limited post-mortem examination on my child, which involves keeping small tissue samples as blocks and slides and may involve taking photographs, X-rays and scans. These will be kept as part of the medical record and may be used for **medical education, training, audit and research**. [See also section 3.]

Please say what you **authorise** to be examined:

- head
- chest
- abdomen
- other (please state what is to be examined)

OR**Section 1C. Authorisation of an external post-mortem examination**

I am the parent/guardian of _____

and I **authorise** the carrying out of an external post-mortem examination on my baby, which may involve taking photographs* / X-rays* / scans* and small skin samples*. These will be kept as part of the medical record and may be used for **medical education, training, audit and research**. [See also section 3.]

(* please circle what you are authorising)

PAGE 2

Section 2. Authorisation of Retention and Examination of Whole Organs

There may be benefits in retaining whole organs for further examination. If so, you will be asked if you are willing to complete this section. **WHOLE ORGANS WILL ONLY BE RETAINED WITH YOUR AUTHORISATION.**

I authorise the retention of my child's organ(s) _____
[please specify] for further investigation, as this is necessary to better understand my child's cause of death and the effects of treatment.

I understand that blocks and slides will be made from these organs and will be kept as part of the medical record and may be used for **medical education, training, audit and research.**

Section 2a: After the retention for detailed examination

Return to the body: I authorise the hospital to return the organs to my child's body. I understand that this may delay the funeral.

OR

Hospital disposal: I authorise the hospital to arrange for disposal of the organs.

OR

Collection by funeral director: I authorise my funeral director to collect and arrange for disposal of the organs.

Section 2b: Gifting of whole organs for education, training, audit and medical research

I authorise the use for **education, training and/or audit** any whole organs removed as part of the post-mortem examination. [See also section 3.]

AND/OR

I authorise the use for **medical research** of any whole organs removed as part of the post-mortem examination. [See also section 3.]

Section 3. Other requests or conditions

Would you like to make any other requests or conditions about the post-mortem examination or any retention or future use of tissue or organs?

If no, please tick box.

If yes, hospital staff should document here any special authorisations or conditions taken or required for this case:

Signature of member of staff witnessing authorisation**I confirm that**

- I have offered information to the parent(s)/guardian(s) about the procedures involved and the reasons for the investigations requested. I have offered to explain any procedures and options available in the level of detail that the parent(s)/guardian(s) wish and have given any explanations they asked for.
- If only one parent/guardian is present, I have asked whether there is likely to be objection to post-mortem examination from the other parent/guardian.
- I have explained that unless the procedures authorised have already taken place the authorisation can be withdrawn at any time, and how the authorisation can be withdrawn.

Information given: leaflet level 1
 leaflet level 2
 Video tape
 Other
 None

Signature of member of staff witnessing authorisation: _____

Name _____

Job title _____

Position _____

Telephone contact no. _____

Bleep _____

Signature of parent(s) or guardian(s)

The post-mortem examination has been explained to me and I feel I have been provided with enough information to give the authorisation set out in this form.

Name of parent/guardian (BLOCK CAPITALS) _____

Signature _____

Relationship to the child: mother/father/guardian(s) (please circle relationship)

Name of parent/guardian (BLOCK CAPITALS) _____

Signature _____

Relationship to the child: mother/father/guardian(s) (please circle relationship)

Contact Details

NOTES

1. If organs are not to be retained, section 3 must be scored through.
2. One copy of the completed form should be given to the parent(s)/guardian(s), one copy retained in the patient record and a copy given to the pathologist who will perform the post-mortem examination that has been authorised.
3. Information leaflet(s) should also be provided to the parent(s)/guardian(s), and a note of which version of leaflet was given retained in the patient record.
4. If any part of the authorisation is withdrawn within the time limit agreed, all copies of the form should be amended with the date the authorisations are withdrawn and a clear statement who is amending the record and on what evidence, e.g. letter, telephone conversation, etc.
5. If any procedures or uses of material are envisaged which are not pre-printed on this form, separate authorisation **MUST** be obtained for these and recorded in section 3. In particular, if any extra tissue is to be taken at post-mortem examination for use in research, specific authorisation for this must be documented in section 3.

THE POST-MORTEM EXAMINATION OF A BABY OR CHILD – BASIC INFORMATION LEAFLET

Summary

The post-mortem examination is an important medical examination to try to find the cause of your baby/child's death.

Ideally the post-mortem examination should take place within a day or two of death.

Your child's face, hands and feet are not normally affected by the post-mortem examination.

You should be able to see and hold your child again after the post-mortem examination.

You, hospital staff or funeral directors can take pictures of your baby before the post-mortem examination if you wish.

The final results of the examination will usually be available in 21 days and a copy is sent to your general practitioner. You can request a copy of the report.

Whole organs will only be kept if we have your authorisation.

If you do not wish a full post-mortem examination, talk to your doctor about other tests that may be done.

Ask as many questions as you wish.

Information about a baby or child's post-mortem examination

We are sorry your child has died and offer you our sympathy. As long as your child remains in our care, he/she will be treated with dignity and respect.

We understand that this is a very difficult time for you and it may be hard to consider a post-mortem examination. This leaflet has been written (with the help of other bereaved parents) to give you clear information about the reasons for doing a post-mortem examination and what you would need to decide.

What do I need to know?

People have different views on how much information they want about a post-mortem examination. You should ask as many questions and read as much information as you want.

If you would prefer not be given any further information about the post-mortem examination, please say so. If, on the other hand, you would like more detail or would like to discuss it with another health professional (such as a pathologist), please ask. There is a second booklet with more detailed information about what is involved in post-mortem examinations. Let us know if you want to have this.

Why do a post-mortem examination?

A post-mortem examination can help families understand why their child died. Sometimes families ask questions that can only be answered with information from a post-mortem examination. It is also possible that the information gained may benefit other families who suffer from similar problems in the future. However, even a post-mortem examination can not always provide a reason for the death, although it may help to answer questions that you or the doctors caring for your child may have. The main reasons for a post-mortem examination are to:

- identify the cause of death;
- confirm the nature of the illness if this is not already known;
- identify conditions that may not have been diagnosed;
- identify complications or side-effects of treatments and drugs;
- help plan future pregnancies and care in pregnancies; and
- diagnose and treat conditions that might affect other members of the family.

The following notes refer to sections in the authorisation form for post-mortem examination.

Section 1: Authorisation of a post-mortem examination

What is a post-mortem examination?

A post-mortem is an examination of a body after death. It is also called an autopsy. Post-mortem examinations are carried out by pathologists – doctors who specialise in the diagnosis of disease and the identification of the cause of disease. Paediatric or perinatal pathologists have further training in disorders that affect babies and children.

What happens in a full post-mortem examination? (Section 1a)

A full post-mortem examination includes an external and an internal examination. It is done with the same care that would be used if the child were having an operation. If you wish to have a more detailed explanation of a full post-mortem examination, please see the other booklet. Small tissue blocks and slides, photographs and X-rays will be made and may be kept as part of the medical record. The note to section 1 explains what this means. Your child's face, hands and feet will not normally be affected by the examination and you should be able to see and hold your child afterwards if you wish.

Are there different options available? (Section 1b and 1c)

If you do not want to agree to a full post-mortem examination, you might consider a limited examination. The doctor or other health professional who discusses the post-mortem examination with you will be able to explain what the options are. Usually, it means that only certain parts of your child's body are examined. Tissue block samples and slides, photographs and x-rays may be made in the same way as for a full post-mortem examination.

The external examination: an even more limited post-mortem examination is an external examination of a stillborn child or fetus, where only images and possibly small skin samples are taken with your authorisation. This is intended only as a check of your baby to look for an abnormality.

However, limited or external examinations provide only limited information about your child's cause of death or illness, whereas a full post-mortem examination will always provide more information. Hospital staff may advise that a limited examination would not provide any useful information and so should not be undertaken.

When is a post-mortem done?

Post-mortem examinations are usually carried out within 1–3 working days of death occurring. They take place in the mortuary. If, because of your religion you must have a funeral within 24 hours, please let us know and we will try to undertake the post-mortem within this time.

Section 1: Authorisation of uses of the medical record

What can be done with the medical record?

Tissue blocks and slides, photographs, X-rays and other images taken during the post-mortem examination will form part of your child's medical record. They may be useful for the family in future, for example, to diagnose conditions in other family members or if more information becomes available about the condition the child may have had. They could also be used for medical education, audit and research. Medical education includes teaching and training all types of doctors, nurses and health professionals so they can provide the best care for patients in the future. Audit means checking the quality of care, procedures and tests to make sure they continue to meet the highest standards.

Medical research may benefit other patients. For example, when a new disease or health problem emerges, examining tissue on a wide scale may provide clues about how and why the disease emerged, and how to respond. This happened with the disease known as new variant CJD after the BSE scare in cattle.

If any photographs could identify your child, you would be asked specifically for your permission before they could be used. If extra tissue or images are requested specifically for education, audit or research you would be asked to give separate permission for this.

What are tissue samples, blocks and slides?

Although some information can be obtained from looking directly at organs and tissues in a post-mortem examination, often the only way to understand properly what has happened is to look at small tissue samples under the microscope. These samples are very small, slightly thicker but no larger than a standard postage stamp.

Section 2: Retention and examination of whole organs

Will any organs be kept?

There may be benefits in keeping a whole organ to carry out a more detailed examination. This will usually be the case if there is an abnormality of the brain, but sometimes the pathologist may need to examine a heart or other organs with a congenital abnormality. Organs will not be retained without your authorisation.

If this is discussed with you, there are a number of other options to consider, such as what happens to the organs afterwards. These are set out in section 2.

Section 3: Other requests or conditions

Can I make any conditions?

If you wish to make any special request or condition, please say so in section 3. For example, there may be religious requirements that you need to have followed, or you may wish to allow some organs to be used for research but not others.

What happens after the examination has been completed?

Care is taken during and after the examination so that your child can be dressed in his/her own clothes, and you may see your child after the examination. Your child's skin and colouring will naturally change after death whether or not a post-mortem examination has been carried out.

Can I find out the results of the post-mortem?

Yes. The pathologist will write a preliminary report within 2 days but some tests will take a few weeks, and a final report should be sent to the doctor caring for your child, normally within 21 days. A copy will also be sent to your general practitioner (GP). You will be offered an appointment to discuss the results either at the hospital or with your own GP. You can have a copy of the report if you wish to have one.

Why do I have to sign the authorisation form?

Unless it has been instructed by the Procurator Fiscal, the doctors need your authorisation before they can carry out the post-mortem examination. A written record of your decision makes it clear to everyone what you have, and have not, agreed to. If you change your mind before the post-mortem has taken place you can withdraw your authorisation – even after signing. The hospital staff will tell you how much time you have in which to do this, and who you should contact. If you authorise the use of the medical record or

organs, you can change your mind at any time, unless the medical records or organs have already been used for authorised purposes. Again, you will be told who you should contact.

How long do I have to decide?

You should take as much time as you need to make a decision, although in practice there is a time limit because of changes that take place after death naturally. There are also some tests that are better done sooner rather than later. The hospital staff should make sure you have enough information to decide if you wish to give your authorisation. They will discuss the alternatives with you. Although they may recommend a particular option, it is important that you understand and come to your own decision. They will ask you whether you have understood the information you have been given and feel able to make a decision. If you are not sure, say so.

We hope this information is helpful but please ask if there is more information you need.

THE POST-MORTEM EXAMINATION OF A BABY OR CHILD – FURTHER INFORMATION LEAFLET

Index

- 1) Post-mortem examination
- 2) Tissue samples, blocks and slides
- 3) Uses of the medical record
- 4) Genetic testing
- 5) Organ retention
- 6) Conditions and requests
- 7) Standards
- 8) Disagreement about post-mortem examination
- 9) Further information

This booklet is intended to be read along with the basic information leaflet (1) and contains more information about the post-mortem examination itself, retention of organs and tissue blocks and slides and the uses of the medical record (see index).

1. What happens in a post-mortem examination?

A post-mortem examination is not just an internal examination, but includes the clinical history, photography, x-rays and external examination as well as many possible tests including virology (the study of viruses), microbiology (the study of bacteria) and genetic investigations (which can vary from chromosome examination to identification of a specific gene).

Your child will have a careful external examination with documentation of weight and various measurements to see how he/she has grown. There will then be two openings made to examine the internal organs, one in the chest and abdomen and one on the back of the head. This allows the pathologist to remove the organs from the body and examine each organ in detail. Small tissue samples will be taken from each organ to be examined under the microscope, swabs, fluids or very small tissue samples may be taken and made into blocks and slides for other tests such as virology, microbiology, biochemistry and genetics if indicated. (See *tissue samples, blocks and slides*.) In some rare cases it may also be felt that small samples should be stored frozen, for later studies using biochemical or genetic tests.

Usually genetic tests would be undertaken to make a specific diagnosis in your child, but occasionally they may have implications for the whole family. If this is the case, you will be consulted and the implications discussed with you (see *genetic tests*).

The organs are all put back in the body unless you have given authorisation for their retention, and after the examination, the body is carefully restored, usually by a mortuary technician, in such a way that when fully clothed you cannot see the incisions. You should be able to see and hold your child after the examination if you wish.

2. What are tissue samples, blocks and slides?

Tissue samples are usually just a small part of an organ. Where a baby is very small, (for example a fetus before 24 weeks' gestation) and the organs are tiny, the pathologist may need to take a larger piece of an organ but will be careful not to take the whole organ. These tissue samples are placed in formalin (a process called fixation) and are often placed directly into plastic cassettes. The tissue is then chemically treated to remove water which is replaced by wax. This produces a tissue block which is a hard block attached to the cassette and from which a very thin section can be cut by a biomedical scientist. This thin section (ten times thinner than a human hair) is mounted on a glass slide before being stained. A very large number of sections can be cut from one tissue block, and a number of different stains can be used to show different features. Tissue blocks and glass slides are stored in special cabinets and are kept securely in laboratories that keep very good records and where access to the laboratory is controlled. These techniques are the same as those used to examine tissue from living patients.

After tissue blocks have been prepared, there may be slivers or small samples of tissue remaining. These will be disposed of by the hospital.

3. Uses of the medical record

What can be done with the medical record?

If you have given your authorisation for a post-mortem examination, then the tissue blocks and slides become part of the medical record of your child. The medical record also consists of the case notes, photographs and X-rays.

It is an important part of ensuring the quality of medicine that work is routinely audited, as recommended by the General Medical Council in their booklet *Good Medical Practice*. This means that checks are made to ensure that the work of medical staff is as accurate as possible by comparing it against recognised standards.

In addition to audit, the photographs, and X-rays taken of your child may have useful lessons or rare conditions that could educate other doctors. Examining tissue is one of the most important ways in which doctors learn about illness and how to treat it. Students training to be doctors need to watch and learn about post-mortem examinations, and discuss the findings with an experienced doctor. In the same way, glass slides can be used to teach other doctors or as part of a test in a scheme such as the national paediatric pathology external quality assurance scheme which regularly tests paediatric and perinatal pathologists' knowledge.

The blocks and slides which form part of the medical record can also be used for medical research. Medical research may benefit other patients. For example, when a new disease or health problem emerges, examining tissue on a wide scale may provide clues about how and why the disease emerged, and how to respond. This happened with the disease known as variant CJD after the BSE scare in cattle.

Sharing information between doctors and hospitals is also very important for public health surveillance - making sure that infectious diseases do not spread throughout the local or national population.

If your child's medical records were to be used in this manner, they would be used anonymously and any identifying features removed.

What about research?

Research is a valuable part of medicine and is how new understanding of disease processes can help in the search for new treatments. Research can vary from a simple study reviewing diagnoses already made to see if there is a new pattern to more complex tests involving gene probes that have only recently been discovered. All research is governed by research ethics committees which might be in the local area (research ethics committees - RECs) or that cover a number of areas (multicentre research ethics committees - MRECs). Both RECs and MRECs have members of the public on the committee.

You can ask if you might see the results of any research that your child's organs or tissue were involved in, but it may not be possible to identify an individual's contribution to a research study. The research institution will have records of its publications, and may have a website giving details of the sort of research it carries out. You should be able to obtain details of the sort of research carried out by the lead researcher and the institution.

What about genetic testing?

Genetic investigations can be important if a baby dies during pregnancy or in the first few weeks of life, to try and find out if the cause is hereditary and if there is a chance of this happening again during a subsequent pregnancy. Genetic tests vary from the examination of chromosomes (often from a blood or skin sample) to those involving specific probes looking for a particular gene linked to a known disease. Simple tests for diagnosis will be done if necessary as part of the post-mortem examination, but a test that might have major implications for the whole family will only be done after discussion with you.

5. Organ retention

The body contains many organs such as the brain, heart, lungs and liver. Each organ carries out many different functions and is composed of different tissues. The brain is extremely soft and in order to examine it thoroughly it has to be hardened in fixative, often for several weeks. Neuropathologists are doctors who specialise in the study of disorders of the brain and spinal cord. They may not be in the same hospital as the post-mortem is carried out and it may take some time to get the results of a neuropathological examination.

What happens after the retention and examination of an organ?

If you authorise the retention of an organ for further examination, you need to consider how it might be dealt with after the examination is complete. If the examination or a preliminary examination can be completed before the funeral, the organ can be returned to the body, and you might wish to consider delaying the funeral to allow this to happen. You should discuss with the hospital how long the funeral would need to be delayed.

If you do not feel you need to have the organs returned to the body before the funeral, you can ask the funeral director who is making the funeral arrangements to arrange for the later disposal of organs. Alternatively, the hospital can arrange this for you and you may wish to ask for more details about what the hospital's arrangements for disposal are.

You may feel that you would like more use to be made of any organ that you authorise to be retained for diagnosis. There are many research studies in different areas of medicine that could benefit from a donation, and a gift such as this would be appreciated and could help in research or education of future doctors. Please discuss this with the person who is explaining the post-mortem, and they should know who to ask about what can be done.

If you authorise the retention of an organ for education, audit or research it will usually not be returned and will be disposed of by the hospital or researcher once the purpose for which it has been retained has been completed.

6. Conditions and requests

What sort of conditions and requests can I make?

You may have specific religious requirements about the timing of the funeral or washing of the body. If you do, please tell the hospital staff and note it on the form. You may wish a special item of clothing or a special soft toy to be with your child during and after the examination, or photographs to be taken while your child is wearing his/her own clothes.

If there is specific research that you would like your child's organs and tissue to be donated to, or if there are specific types of research that you would object to, then the authorisation form is the place to record those wishes. You may want the organs to be held only for a limited period of time. Again, if so, please say so on the authorisation form.

7. Standards

How do I know that only what I have authorised will be carried out?

NHS Quality Improvement Scotland has written standards for post-mortem examinations that must be followed by NHS personnel in Scotland. These are available on their website (<http://www.clinicalstandards.org/nhsqis/>) and you can ask for a copy to read. One of the standards is that there is a check on what has been authorised and what is then carried out by the pathology department. The Royal College of Pathologists has also published guidelines about post-mortem practices, and has published patient leaflets and guidance about the retention of tissues and organs at post-mortem examinations.

8. What if parents disagree about a post-mortem examination?

Where both parents are available, it is always best that they agree on whether or not a post-mortem examination can be done. Where only one parent is available at the hospital, he or she will be asked if they think the other parent would object. The post-mortem examination can go ahead if only one parent authorises it. However, if the other parent objects or would be likely to object, then usually the post-mortem examination would not be done. There may be unusual circumstances in which parents disagree strongly over whether a post-mortem examination should be done. Where this disagreement cannot be resolved through discussion, the post-mortem examination would not usually go ahead.

9. Further information

What else can I read about post-mortem examination?

Pregnancy loss and the death of a baby: Guidelines for professionals, SANDS 1995

Standards for the management of post-mortem examinations: NHS Quality Improvement Scotland April 2003

Royal College of Pathologists: *Guidelines on Autopsy Practice*, September 2002

Medical Research Council (MRC). *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* MRC 2001.

The hospital will have a list of local and national organisations who can offer support and further information.

AUTHORISATION FOR THE HOSPITAL POST-MORTEM EXAMINATION OF AN ADULT

This form and the information leaflet that goes with it are:

- to help you understand what is involved in a hospital post-mortem examination; and
- to provide a record for you and for the hospital about what you want to happen if you decide to authorise a post-mortem examination.

Please read the accompanying information leaflet very carefully.

The information leaflet you have been given is a short one, giving important general information. There is another information leaflet if you wish to be given more detailed information and you will be asked if you wish to have this leaflet as well. **If there is anything you do not understand, or want to know more about, please ask the hospital staff.**

If you decide to authorise a post-mortem examination, please complete this form in discussion with the hospital staff, and check that all the information on this form is right. If it is, sign your name at the end of the form. The member of hospital staff who has discussed the examination with you will sign the form as well, and give you a copy to keep.

You should take as long as you need to think about whether you wish to authorise a post-mortem examination and what you would want to happen afterwards. Please note: the post-mortem examination may take place later on the same day on which you give your authorisation.

Box for Contact Details

PAGE 1

Section 1A. Authorisation of a full post-mortem examination

I am the nominated representative/nearest relative of

I have told hospital staff if I am aware that the person named above left any instructions about post-mortem examination and I am not aware that the person named above would have objected to it.

I **authorise** the carrying-out of a full post-mortem examination on the person named above, which involves keeping small tissue samples as blocks and slides and may involve taking photographs and X-rays. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 3.]

OR

Section 1B. Authorisation of a limited post-mortem examination

I am the nominated representative/nearest relative of

I have told hospital staff if I am aware that the person named above left any instructions about post-mortem examination and I am not aware that the person named above would have objected to it.

I **authorise** the carrying-out of a limited post-mortem examination on the person named above, which involves keeping small tissue samples as blocks and slides and may involve taking photographs and X-rays. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 3.]

Please say what you **authorise** to be examined:

head

chest

abdomen

other (please state what is to be examined)

PAGE 2**Section 2. Authorisation of Retention and Detailed Examination of Whole Organs**

There may be benefits in retaining whole organs for further examination. If so, you will be asked if you are willing to complete this section. **WHOLE ORGANS WILL ONLY BE RETAINED ON INSTRUCTIONS LEFT BY THE DECEASED OR WITH YOUR AUTHORISATION.**

I **authorise** the retention of the deceased's organ(s) _____
[please specify which] for further investigation, as this is necessary to better understand the deceased's cause of death and the effects of treatment.

I understand that blocks and slides will be made from these organs and may be kept as part of the medical record and that they may be used for medical education, training, audit and research.

Section 2a: After the retention for detailed examination

Return to the body: I authorise the hospital to return the organs to the body. I understand that this may delay the funeral.

OR

Hospital disposal: I authorise the hospital to arrange for disposal of the organs.

OR

Collection by funeral director: I authorise my funeral director to collect and arrange for disposal of the organs.

Section 2b: Gifting of whole organs for education, training, audit and medical research

I **authorise** the use for **education, training and/or audit** any whole organs removed as part of the post-mortem examination. [See also section 3.]

AND/OR

I **authorise** the use for **medical research** of any whole organs removed as part of the post-mortem examination. [See also section 3.]

Section 3. Other requests or conditions

Would you like to make any other requests or conditions about the post-mortem examination or any retention or future use of tissue or organs?

If no, please tick box.

If yes, hospital staff should document here any special authorisations or conditions taken or required for this case:

Signature of member of staff witnessing authorisation

I confirm that

- I have asked if the deceased left any instructions about post-mortem examination including instructions about retention of organs. I have checked whether the deceased had any objections. The authorisations given on this form do not contradict any objections that the deceased is believed to have had on these matters.
- I have attached a copy of any instructions left by the deceased or a note of any objections he or she is believed to have had to this form.
- I have offered information to the deceased's nominated representative/nearest relative about the procedures involved and the reasons for the investigations requested. I have offered to explain any procedures and options available in the level of detail that the nominated representative/nearest relative wish and have given any explanations asked for.
- I have explained that unless the procedures authorised have already taken place the authorisation given by the nominated representative/nearest relative can be withdrawn at any time, and how the authorisation can be withdrawn.

Information given: Leaflet Level 1
Leaflet Level 2
Video tape
Other
None

Signature of member of staff witnessing authorisation: _____

Name: _____

Job title _____

Position _____

Telephone Contact no. _____

Bleep _____

Signature of authorising person: _____

I am the deceased's nominated representative/nearest relative and I am not aware of anyone with a closer relationship who should be asked if there is an objection to post-mortem examination of the deceased.

The post-mortem examination has been explained to me and I feel I have been provided with enough information to give the authorisation set out in this form.

Name of authorising person (BLOCK CAPITALS) _____

Signature _____

**Relationship to the deceased: nominated representative/husband/wife/
partner/parent/child/other (please circle relationship and if other, explain)**

Contact Details

**If permission was obtained from the deceased's nominated representative/
nearest relative over the telephone for another person to give authorisation:**

**Additional Signature of member of staff who witnessed discussion with the
nominated representative/nearest relative:**

NOTES

1. If organs are not to be retained, section 2 must be scored through.
2. One copy of the completed form should be given to the nominated representative/nearest relative, one copy retained in the patient record and a copy given to the pathologist who will perform the post-mortem examination that has been authorised.
3. Information leaflet(s) should also be provided to the nominated representative/nearest relative, and a note of which version of leaflet was given retained in the patient record.
4. If any part of the authorisation is withdrawn within the time limit agreed, all copies of the form should be amended with the date the authorisations are withdrawn and a clear statement who is amending the record and on what evidence, e.g. letter, telephone conversation, etc.
5. If any procedures or uses of material are envisaged which are not pre-printed on this form, separate authorisation **MUST** be obtained for these and recorded in section 3. In particular, if any extra tissue is to be taken at post-mortem examination for use in research, specific authorisation for this must be documented in section 3.
6. Permission to seek authorisation from a person other than the deceased's nominated representative/nearest relative should only be taken over the telephone exceptionally. All possible steps should be taken to verify the identity of the person whose permission to appoint a substitute is being sought. This discussion must be witnessed by another member of staff.

THE HOSPITAL POST-MORTEM EXAMINATION OF AN ADULT – BASIC INFORMATION LEAFLET

Summary

The post-mortem examination is an important medical examination to find the cause of a person's death.

The person's own wishes about whether or not post-mortem examination should take priority.

If the person asked someone else to make such decisions (a nominated representative), he or she will be asked to consider authorising a post-mortem examination.

If the deceased left no instructions and there is no nominated representative, the nearest relative will be asked whether he or she wishes to authorise a post-mortem examination. There are rules that set out who the nearest relative is.

Ideally the post-mortem examination should take place within a day or two of death.

The person's face, hands and feet are not normally affected by the post-mortem examination.

Relatives should be able to see the body again after the post-mortem examination.

The final results of the examination will usually be available in 21 days and a copy is sent to the deceased's general practitioner. Unless the deceased did not wish this, a copy of the report can be requested by the nominated representative/nearest relative.

Whole organs will only be kept if this was the deceased person's wish or we have authorisation from the nominated representative/nearest relative.

If the nominated representative/nearest relative does not wish to authorise a full post-mortem examination, there may be other tests that may be done. This should be discussed with hospital staff.

Ask as many questions as you wish.

Information about an adult's post-mortem examination

We understand that this is a difficult time for you and it may be hard to consider a post-mortem examination. This leaflet has been written (with the help of bereaved relatives) to give you clear information about the reasons for doing a post-mortem examination and what you would need to decide.

About the authorisation form

Unless it has been ordered by the Procurator Fiscal, the doctors need authorisation before they can carry out a post-mortem examination. If the deceased has left clear instructions that he or she authorises a post-mortem examination and what can be done with his or her body, then these instructions take priority. If he or she had authorised a post-mortem examination, it can take place even if relatives object.

The deceased may have chosen someone else to make such decisions instead. If the hospital knows who this person is, he or she would be the deceased's nominated representative and would be asked whether or not a post-mortem examination should go ahead. The nominated representative can authorise a post-mortem examination even if relatives object.

If the deceased left no instructions and did not nominate someone else to make these kinds of decision, the nearest relative will be the person who is asked to consider authorising a post-mortem examination. There are rules which set out who the nearest relative is and these will be explained to you. You should let hospital staff know if you think there is a nearer relative than you, or if there are other people who you think should be involved in making this kind of decision.

If you have been given this form it is because the hospital thinks you are the deceased's nominated representative or nearest relative and that you are the person who should be asked whether or not to authorise a post-mortem examination. A written record of your decision makes it clear to everyone what you have, and have not, agreed to. If you change your mind before the post-mortem has taken place you can withdraw your authorisation - even after signing. The hospital staff will tell you how much time you have in which to do this, and who you should contact.

Important: before going on with this leaflet, if you are not sure whether you are the person who should be asked to authorise post-mortem examination, because you are not sure you are the person's nominated representative or nearest relative, please explain this and check with hospital staff.

What do I need to know?

People have different views on how much information they want about a post-mortem examination. You should ask as many questions and read as much information as you want.

You may not want to know any more about the post-mortem examination, but would still be willing to authorise it. If, on the other hand, you would like more detail or would like to discuss it with another health professional (such as a pathologist), please ask. There is a second leaflet with more detailed information about what is involved in post-mortem examinations. Let us know if you want to have this.

Why do a post-mortem examination?

A post-mortem examination can provide information about the illness or other cause of a person's death. Sometimes families ask questions that can only be answered with information from a post-mortem examination. It is also possible that the information gained may benefit other families who suffer from similar problems in the future. The post-mortem findings are also very important for the staff who cared for the person who has died. They can use the knowledge to learn about disease and possibly help others in the future. However, even a post-mortem examination can not always provide a reason for the death. The main reasons for a post-mortem examination are to:

- identify the cause of death;
- confirm the nature of the illness if this is not already known;
- identify conditions that may not have been diagnosed;
- identify complications or side-effects of treatments and drugs; and
- diagnose and treat conditions that might affect other members of the family.

The following notes refer to sections in the authorisation form for post-mortem examination.

Section 1: Authorisation of a post-mortem examination

What happens in a full post-mortem examination? (Section 1a)

A full post-mortem examination includes an external and an internal examination. It is done with the same care that would be used if the person were having an operation. If you wish to have a more detailed explanation of a full post-mortem examination, please see the other booklet. Small tissue blocks and slides, photographs and X-rays will be made and may be kept as part of the medical record. The person's face, hands and feet will not normally be affected by the examination and you should be able to see the body afterwards if you wish.

Are there different options available? (Section 1b)

If you do not want to agree to a full post-mortem examination, you might consider a limited examination. The doctor or other health professional who discusses the post-mortem with you will be able to explain what the options are. Usually, it means that only certain parts of the body are examined. Tissue block samples and slides, photographs and X-rays may be made in the same way as for a full post-mortem examination.

However, limited examinations provide only limited information about cause of death or illness. A full post-mortem examination will always provide more information. Hospital staff may advise that a limited examination would not provide any useful information and so should not be undertaken.

Since the person's own wishes about what he or she wished to happen have most importance, you will be asked if you know whether the deceased left any instructions about post-mortem examination, or if you think he or she would have objected to it. If there were instructions, these will be checked and if the deceased would have objected then the post-mortem examination would not take place.

When is a post-mortem done?

Post-mortem examinations are usually carried out within 1-3 working days of death occurring. They take place in the mortuary. If because of the person's religion the funeral must be within 24 hours, please let us know; we will try to undertake the post-mortem within this time.

What happens in a post-mortem examination?

A post-mortem examination is done with the same care that would be used in an operation. It includes an external and an internal examination. If you wish a detailed explanation, please see the other booklet. The person's face, hands and feet will not normally be affected by the examination.

Section 1: Authorisation of uses of the medical record

What can be done with the medical record?

Tissue blocks and slides, photographs, X-rays and other images taken during the post-mortem examination will form part of the person's medical record. Unless the deceased had objected to information being shared with the family, they may be useful for the family in future, for example, to diagnose conditions in other family members or if more information becomes available about the condition the person may have had.

They could also be used for medical education and audit. Medical education includes teaching and training all types of doctors, nurses and health professionals so they can provide the best care for patients in the future. Audit means checking the quality of care, procedures and tests to make sure they continue to meet the highest standards.

The medical record can also be used for medical research that may benefit other patients. For example, when a new disease or health problem emerges, examining tissue on a wide scale may provide clues about how and why the disease emerged - and how to respond. This happened with the disease known as variant CJD after the BSE scare in cattle.

If any photographs could identify the person, you would be asked specifically for your permission before they are used unless the deceased person had authorised this use. If extra tissue or images are requested specifically for education, audit or research you would be asked to give separate permission for this, again unless the person had authorised this to be done.

What are tissue samples, blocks and slides?

Although some information can be obtained from looking directly at organs and tissues in a post-mortem examination, often the only way to understand properly what has happened is to look at small tissue samples under the microscope. These samples are very small, slightly thicker but no larger than a standard postage stamp. (For more detailed information please see the second leaflet.)

Section 2: Retention and examination of organs

Will any organs be kept?

There may be benefits in keeping a whole organ to carry out a more detailed examination. This will usually be the case if there is an abnormality of the brain, but sometimes the pathologist may need to examine a heart or other organs with an abnormality. Organs will not be retained without the deceased's or your authorisation. (For more information on retention and examination of organs, see the second leaflet.)

If this is discussed with you, there are a number of other options to consider, such as what happens to the organs afterwards. If the person had left instructions about these matters, the hospital will follow these instructions.

Section 3: Other requests or conditions

Can I make any conditions?

If you wish to make any special request or condition, please say so in Section 3, for example, if there are religious requirements that you need to have followed or you wish to allow some organs to be used for research but not others.

What happens after the examination has been completed?

Great care is taken during and after the examination so that the body can be seen after the examination and dressed in his/her clothes. The skin and colouring will naturally change after death whether or not a post-mortem examination has been carried out.

Can I find out the results of the post-mortem examination?

Yes, unless the deceased wished his or her medical information to remain confidential. The pathologist will write a preliminary report within 2 days but some tests may take a few weeks, and a final report will be sent to the doctor who had been caring for the person within 21 days. A copy will be sent to the deceased's general practitioner (GP). You may be offered an appointment to discuss the results, or you may wish to see the GP. You can ask for a copy of the report.

What should I know before deciding?

You should take as much time as you require to make a decision although in practice there is a time limit because of changes that take place after death naturally. Also some tests are better done sooner rather than later (see summary). The hospital staff should make sure you have enough information to decide whether you wish to give your authorisation. They will discuss the alternatives

with you. Although they may recommend a particular option, it is important that you understand and come to your own decision. They will ask you to say whether you have understood the information you have been given. If you are not sure, say so.

If you change your mind before the post-mortem examination has taken place you can withdraw your authorisation. The hospital staff will tell you how much time you have in which to do this, and who you should contact. If you give your permission for use of the medical record or organs, permission can be withdrawn at any time unless the medical records or organs have already been used for authorised purposes. Again, you will be told who you should contact.

We hope this information is helpful but please ask if there is more information you need.

THE HOSPITAL POST-MORTEM EXAMINATION OF AN ADULT - FURTHER INFORMATION LEAFLET

Index

- 1) Post-mortem examination
- 2) Tissue samples, blocks and slides
- 3) Uses of the medical record
- 4) Genetic testing
- 5) Organ retention
- 6) Conditions and requests
- 7) Standards
- 8) Disagreement about post-mortem examination
- 9) Further information

This booklet is intended to be read along with the basic information leaflet (1) and contains more information about the post-mortem examination itself, retention of organs and tissue blocks and slides and the uses of the medical record.

1. What happens in a post-mortem examination?

A post-mortem examination is not just an internal examination, but includes the clinical history, photography, X-rays and external examination as well as many possible tests including virology (the study of viruses), bacteriology (the study of bacteria) and genetic investigations (which can vary from chromosome examination to identification of a specific gene). Some of these tests are only very rarely done during a post-mortem examination on an adult.

The body will have a careful external examination. There will then be two openings made to examine the internal organs, one in the chest and abdomen and one on the back of the head. This allows the pathologist to remove the organs from the body and examine each organ in detail. Small tissue samples will be taken from each organ to be examined under the microscope. Swabs, fluids or very small tissue samples may be taken for other tests such as virology, microbiology, biochemistry and genetics if indicated. (See *What are tissue samples, blocks and slides*).

In some rare cases it may also be felt that small samples should be stored frozen, for later studies using biochemical or genetic tests.

Usually genetic tests would be undertaken to make a specific diagnosis in the deceased, but occasionally they may have implications for the whole family. If this is the case, you will be consulted and the implications discussed with you (See *Genetic testing*).

The organs are all returned to the body unless the deceased (or you) has given authorisation for their retention, and after the examination, the body is carefully restored, usually by a mortuary technician in such a way that when fully clothed you cannot see the incisions. You should be able to see the body after the examination if you wish.

2. What are tissue samples, blocks and slides?

Tissue samples are a very small part of an organ. These **tissue samples** are placed in formalin (called fixation) and are often placed directly into plastic cassettes. The tissue is then chemically treated to remove water, which is replaced by wax. This produces a **tissue block**, which is a hard block attached to the cassette and from which a very thin section can be cut by a biomedical scientist. This thin section (ten times thinner than a human hair) is mounted on a **glass slide** before being stained. A very large number of sections can be cut from one tissue block, and a number of different stains can be used to show different features. Tissue blocks and glass slides are stored in special cabinets and are kept securely in laboratories that keep very good records and control access to the laboratory. These techniques are the same as those used to examine tissue from living patients.

After tissue blocks have been prepared, there are sometimes slivers or small samples of tissue remaining. These will be disposed of by the hospital.

3. Uses of the medical record

What can be done with the medical record?

If authorisation for a post-mortem examination has been given, then the tissue blocks and slides become part of the medical record of the deceased. The medical record also consists of the case notes, photographs and X-rays.

It is an important part of ensuring the quality of medicine that work is routinely audited, as recommended by the General Medical Council in their booklet *Good Medical Practice*. This means that checks are made to ensure that the work of medical staff is as accurate as possible by comparing it against recognised standards.

In addition to audit, the photographs, and X-rays taken may have useful lessons or may relate to rare conditions that other doctors could learn about. Examining tissue is one of the most important ways in which doctors learn about illness and how to treat it. Students training to be doctors need to watch and learn about post-mortem examinations, and discuss the findings with an experienced doctor. In the same way, glass slides can be used to teach other doctors or as part of a test in a scheme such as the national Scottish pathology external quality assurance scheme which regularly tests pathologists' knowledge.

Sharing information between doctors and hospitals is also very important for public health surveillance - making sure that infectious diseases do not spread throughout the local or national population.

If the deceased's medical records were to be used in this manner, they would be used anonymously and any identifying features removed.

What about research?

Research is a valuable part of medicine and is how new understanding of disease processes can help in the search for new treatments. Research can vary from a simple study reviewing diagnoses already made to see if there is a new pattern to more complex tests involving gene probes that have only recently been discovered. All research is governed by research ethics committees which might be in the local area (research ethics committees - RECs) or that cover a number of areas (multicentre research ethics committee - MRECs). Both RECs and MRECs have members of the public on the committee.

You can ask if you might see the results of any research that the person's organs or tissue were involved in, but it may not be possible to identify an individual's contribution to a research study. The research institution will have records of its publications, and may have a website giving details of the sort of research it carries out. You should be able to obtain details of the sort of research carried out by the lead researcher and the institution.

4. Genetic testing

Genetic tests vary from the examination of chromosomes (often from a blood or skin sample) to those involving specific probes looking for a particular gene linked to a known disease. Simple tests for diagnosis will be done if necessary as part of the post-mortem examination, but a test that might have major implications for the whole family will only be done after discussion with you. Genetic testing is rarely carried out in post-mortem examination of adults.

5. Organ retention

The body contains many organs, such as the brain, heart, lungs and liver. Each organ carries out many different functions and is composed of different tissues. The brain is extremely soft and in order to examine it thoroughly it has to be hardened in fixative often for several weeks. Neuropathologists are doctors who specialise in the study of disorders of the brain and spinal cord. They may not be in the same hospital as the post-mortem is carried out and it may take some time to get the results of a neuropathological examination.

What happens after the retention and examination of an organ?

If the person left instructions authorising the retention of organs for further examination or gifted them for research, the wishes of the deceased will be followed, as will any instructions concerning disposal.

If you authorise the retention of an organ for further examination, you need to consider how it might be dealt with after the examination is complete. If the examination or a preliminary examination can be completed before the funeral, the organ can be returned to the body, and you might wish to consider delaying the funeral to allow this to happen. You should discuss with the hospital how long the funeral would need to be delayed.

If you do not feel you need to have the organs returned to the body before the funeral, you can ask the funeral director who is making the funeral arrangements to arrange for the later disposal of organs. Alternatively, the hospital can arrange this for you and you may wish to ask for more details about what the hospital's arrangements for disposal are.

You may feel that you would like more use to be made of any organ that you authorise to be retained for diagnosis. There are many research studies in different areas of medicine that could benefit from a donation, and a gift such as this would be appreciated and could help in research or education of future doctors. Please discuss this with the person who is explaining the post-mortem, and they should know who to ask about what can be done.

If you authorise the retention of an organ for education, audit or research it will usually not be returned and will be disposed of by the hospital or researcher once the purpose for which it has been retained has been completed.

6. Conditions and requests

What sort of conditions and requests can I make?

You may have specific religious requirements about the timing of the funeral or washing of the body. If you do, please tell the hospital staff and ask them to note these in section 3 of the form.

If there is specific research that you would like the person's organs and tissue to be donated to, or if there are specific types of research that you would object to, then the authorisation form is the place to record those wishes. You may want the organs to be held for only a limited period of time. Again, if so, please say so on the authorisation form.

7. Standards

How do I know that only what has been authorised will be carried out?

NHS Quality Improvement Scotland has written standards for post-mortem examinations that must be followed by NHS personnel in Scotland. These are available on their website (www.clinicalstandards.org/nhsqis/) and you can ask for a copy to read. One of the standards is that there is a check on what has been authorised and what is then carried out by the pathology department. The Royal College of Pathologists has also published guidelines about post-mortem practices, and has published patient leaflets and guidance about the retention of tissues and organs at post-mortem examinations.

8. What if the relatives disagree about a post-mortem examination?

It is always best where all those close to the deceased agree on whether or not a post-mortem examination can be done. Where the deceased left instructions authorising or objecting to post-mortem examination, use of his or her medical record and use of organs, doctors will usually act on these instructions. If the deceased nominated a person to make decisions for them and the hospital is made aware of this, then doctors will act in accordance with the views of the nominated representative.

If the deceased did not leave instructions or nominate a representative, then the person's nearest relative would be the person asked to consider authorising a post-mortem examination.

The person's nearest relative would be determined in descending order of priority according to this list:

- husband, wife or partner (see below)
- son or daughter
- father or mother
- brother or sister
- grandfather or grandmother
- grandson or granddaughter
- uncle or aunt
- nephew or niece.

Where there is more than one possible nearest relative, for example where there is no surviving husband or wife but there are a son and a daughter, the eldest child would be treated as the nearest relative. Illegitimate children have the same rights as legitimate ones.

Unmarried partners should have the same rights to give authorisation as husbands or wives, regardless of whether they are of the same sex as the deceased. However, in line with current law, unmarried partners must have been living with the person as if they were husband or wife for a reasonable time, not less than 6 months. Where the deceased was divorced or permanently separated from a husband or wife, the husband or wife loses the right to give or withhold authorisation of a post-mortem examination.

Where only one of the close relatives is available at the hospital, he or she will be asked if they think the other close relatives would object. The post-mortem examination can go ahead if the nominated representative or the nearest relative authorises it. However, if the other close relatives object or would be likely to object, then usually the post-mortem examination would not be done. There may be unusual circumstances in which relatives disagree strongly over whether a post-mortem examination should be done. Where disagreement cannot be resolved through discussion, the post-mortem examination would not usually go ahead.

9. Further information

What else can I read about post-mortem examination?

Standards for the management of post-mortem examinations: NHS Quality Improvement Scotland April 2003

Royal College of Pathologists: *Guidelines on Autopsy Practice*, September 2002

Medical Research Council (MRC). *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* MRC 2001.

The hospital will have a list of local and national organisations who can offer support and further information.

AUTHORISATION FORM FOR USE OF MATERIAL RETAINED FROM A POST-MORTEM EXAMINATION INSTRUCTED BY THE PROCURATOR FISCAL ON AN ADULT

This form and the information leaflet that goes with it are:

- to help you understand what would be involved in authorising medical education, training, audit and research to take place as a result of material being retained from a post-mortem examination required by the Procurator Fiscal;
- to provide a record for everyone about what you want to happen if you decide to give your authorisation.

Please read the accompanying information leaflet very carefully.

It gives important general information, and should be read with the leaflet provided by the Procurator Fiscal's office [*name of leaflet*].

If there is anything you do not understand, or want to know more about, please ask the person who is discussing this with you.

If you decide to give your authorisation, please complete this form in discussion with the person who has approached you for authorisation, and check that all the information on this form is correct. If it is, sign your name at the end of the form. The person who has discussed the form with you will sign the form as well, and give you a copy to keep.

You should take as long as you need to think about whether you wish to authorise medical education, training, audit and research to take place in respect of the material retained following the post-mortem examination.

Box for Contact Details

PAGE 1**Section 1. Authorisation of the use of post-mortem examination material kept as part of the medical record**

I am the nominated representative/nearest relative of

I have mentioned any instructions I am aware of that the person named above left about post-mortem examination. I understand that the post-mortem examination instructed by the Procurator Fiscal involves keeping small tissue samples as blocks and slides and may involve taking photographs, X-rays and scans. I understand these will be kept as part of the medical record of the deceased.

I **authorise** the tissue samples, blocks and slides to be used for **medical education, training, audit and research**. [See also section 3.]

Section 2. Authorisation of the Use of Whole Organs

You will have been told by the Fiscal whether whole organs need to be or have been retained for further examination. You will be advised by the person seeking authorisation if you need to complete this section. **WHOLE ORGANS WILL ONLY BE RETAINED FOR MEDICAL USES IF THE DECEASED LEFT INSTRUCTIONS TO THAT EFFECT, OR IF YOU GIVE YOUR AUTHORISATION.**

I **authorise** the use for **education, training, audit and research** of any whole organs removed as part of the post-mortem examination. [See also section 3.]

Section 3. Other requests or conditions

Would you like to make any other requests or conditions about the retention or future use of tissue or organs? If no, please tick box.

If yes, the person seeking authorisation should document here any special authorisations or conditions:

Signature of person witnessing authorisation:

I confirm that

- I have asked if the deceased left any instructions about medical uses of post-mortem examination material, including instructions about retention of organs. I have checked whether the deceased had any objections. The authorisations given on this form do not contradict any objections that the deceased is believed to have had on these matters.
- I have attached to this form a copy of any instructions left by the deceased or a note of any objections he or she is believed to have had.
- I have offered information to the deceased's nominated representative/nearest relative about the procedures involved and the reasons for the medical uses of the results of the post-mortem examination requested. I have offered to explain any procedures and options available in the level of detail that the nominated representative/nearest relative wish and have given any explanations asked for.
- I have explained that authorisation of medical uses of the medical record cannot be withdrawn. I have explained that, until the authorised research use of organs has taken place, the authorisation given by the nominated representative/nearest relative can be withdrawn at any time. I have also explained how the authorisation for that purpose can be withdrawn.

Information given: Leaflet
Video tape
Other
None

Signature: _____

Name: _____

Job title/position _____

Telephone contact no. _____

Bleep _____

Signature of authorising person: _____

I am the deceased's nominated representative/nearest relative and I am not aware of anyone with a nearer relationship who should be asked if there is an objection to medical uses of the medical record/whole organs of the deceased.

The medical uses of the post-mortem examination material have been explained to me and I feel I have been provided with enough information to give the authorisation set out in this form.

Name of authorising person (BLOCK CAPITALS)

Signature _____

Relationship to the deceased: nominated representative/husband/wife/partner/parent/child/other (please circle relationship and if other, explain)

Contact Details

If permission was obtained from the deceased's nominated representative/nearest relative over the telephone for another person to give authorisation:

Additional Signature of person who witnessed discussion with the nominated representative/nearest relative:

NOTES

1. If whole organs are not to be used for research, section 2 must be scored through.
2. One copy of the completed form should be given to the nominated representative/nearest relative, one copy retained in the patient record and a copy given to the pathologist who will perform or has performed the post-mortem examination instructed by the Procurator Fiscal.
3. An information leaflet should also be provided to the nominated representative/nearest relative, and a note of which version of leaflet was given retained in the patient record.
4. If any part of the authorisation is withdrawn within the time limit agreed, all copies of the form should be amended with the date the authorisations are withdrawn and a clear statement who is amending the record and on what evidence, e.g. letter, telephone conversation, etc.
5. If any procedures or uses of material are envisaged which are not pre-printed on this form, separate authorisation **MUST** be obtained for these and recorded in section 3.
6. Permission to seek authorisation from a person other than the deceased's nominated representative/nearest relative should only be taken over the telephone exceptionally. All possible steps should be taken to verify the identity of the person whose permission to appoint a substitute is being sought. This discussion must be witnessed by another appropriate person.

PROCURATOR FISCAL POST-MORTEM EXAMINATION OF AN ADULT – INFORMATION LEAFLET

SUMMARY

The post-mortem examination is an important medical examination required by the Procurator Fiscal to find the cause of a person's death. Your authorisation is not needed for this.

Authorisation is needed for medical education, training, audit or research to be carried out on any materials obtained as a result of the post-mortem examination.

Authorisation could be in instructions left by the person deceased about what they would wish to happen in the event of death.

If the person asked someone else to make such decisions (a nominated representative), he or she would be asked to consider authorising the use of materials obtained at post-mortem examination.

If the deceased left no instructions and there is no nominated representative, the nearest relative would be asked whether he or she wishes to authorise the use of materials obtained at post-mortem examination. There are rules that set out who the nearest relative is.

Whole organs are sometimes kept to assist the diagnostic examination. They will only be kept for other medical uses if this was the person's wish or we have the authorisation of the person's nominated representative/nearest relative.

Ask as many questions as you wish.

INFORMATION ABOUT MEDICAL USES OF MATERIAL OBTAINED AT AN ADULT'S POST-MORTEM EXAMINATION

We understand that this is a very difficult time for you and it may be hard to consider medical uses of the post-mortem examination required by the Procurator Fiscal. This leaflet has been written to give you clear information about the reasons why you might wish to consider authorising medical uses of material obtained from the post-mortem examination, and what you would need to decide.

The post-mortem examination

It will have been explained to you that the Procurator Fiscal has decided that a post-mortem examination needs to be carried out upon the deceased.

The post-mortem examination, and the tests which are later performed in the laboratory, are undertaken to find the cause and mechanism of death. Your authorisation is not needed for this to happen. However, we do need authorisation if we are to do further studies to learn more about the condition which caused the death of the deceased. This leaflet tells you about the possibilities for helping with this kind of medical education, audit, training and research, and tries to answer some of the questions you may have.

If the deceased has left clear instructions that he or she authorises what can be done with his or her body in the event of a post-mortem examination being undertaken, then these instructions take priority. That means that if he or she had authorised the keeping of materials for medical education, training, audit or research in the event of a post-mortem examination, this can be done even if relatives object.

The deceased may have chosen someone else to make such decisions. If so, he or she would be the deceased's nominated representative and would be asked whether or not materials obtained at post-mortem examination can be used for medical purposes. The nominated representative can authorise this even if relatives object.

If the deceased left no instructions and did not nominate someone else to make these kinds of decision, the nearest relative will be the person who is asked to consider authorising the medical use of materials obtained at the post-mortem examination. There are rules which set out who the nearest relative is and these will be explained to you. You should let us know if you think there is a nearer relative than you or if there are other people whom you think should be involved in making this kind of decision.

You have been given this form because we think you are the deceased's nominated representative or nearest relative and that you are the person who should be asked whether or not to authorise the medical use of materials obtained at the post-mortem examination. A written record of your decision makes it clear to everyone what you have, and have not, agreed to. Once you have agreed to the medical record obtained at post-mortem examination being used for medical education, training and audit, this authorisation cannot be withdrawn. However, if you change your mind about donating material for medical research before the materials have been used for such research you can withdraw your authorisation, even after signing. The person discussing the form with you will tell you how to do this and who you should contact.

Important: before going on with this leaflet, if you are not sure whether you are the person who should be asked to authorise post-mortem examination, because you are not sure you are the person's nominated representative or nearest relative, please explain this to the person who is discussing the form with you.

What do I need to know?

People have different views on how much information they want about the post-mortem examination itself and the possible medical uses of material derived from it. You should ask as many questions and read as much information as you want.

You may not want to know any more about the post-mortem examination itself but would nonetheless be willing to help. You may not wish to know more about the post-mortem examination, but may want to be told more about the kind of research which might be carried out. If, on the other hand, you would like more detail or would like to discuss it with another health professional (such as a pathologist), please ask.

The following notes refer to sections in the authorisation form for medical uses of the post-mortem examination.

SECTION 1: AUTHORISATION FOR USING POST-MORTEM EXAMINATION MATERIAL KEPT AS PART OF THE MEDICAL RECORD

Small tissue blocks and slides, photographs and X-rays are made as part of the post-mortem examination.

What are tissue samples, blocks and slides?

Although some information can be obtained from looking directly at organs and tissues in a post-mortem examination, often the only way to understand properly what has happened is to look at small tissue samples under the microscope. These samples are very small, slightly thicker but usually no larger than a standard postage stamp. These tissue samples are chemically treated to remove water which is replaced by wax. This produces a tissue block from which a very thin section (ten times thinner than a human hair) can be cut. It is mounted on a glass slide before being stained. A very large number of sections can be cut from one tissue block, and a number of different stains can be used to show different features. (For more detailed information, please ask.)

Using post-mortem examination material kept as part of the deceased's medical record?

Once the post-mortem examination instructed by the Procurator Fiscal has been completed, the tissue samples, blocks and slides, and any records made as part of the post-mortem examination, will become part of the medical record of the deceased. However, they cannot be used for any purposes other than those related to the Procurator Fiscal's investigation of the death unless appropriate authorisation has been given.

Since the person's own wishes about what he or she wished to happen have most importance, you will be asked if you know whether the deceased left any instructions about keeping and using material obtained at post-mortem examination for medical purposes or if you think he or she would have objected to it. If there were instructions, these would be checked and if the deceased would have objected then the material will not be kept or used for these purposes.

If the deceased left no instructions and you do not believe he or she would have had any objections, you can authorise the medical use of these tissue samples, blocks and slides, photographs and scans forming part of the deceased's medical record. Once you have agreed to the medical record obtained at post-mortem examination being used for medical education, training and audit, this authorisation cannot be withdrawn. However, if you change your mind about donating material for medical research before the materials have been used for such research you can withdraw your authorisation, even after signing.

Why authorise using post-mortem examination material kept as part of the deceased's medical record?

Unless the deceased had objected to information being shared with the family, they may be useful for the family in future, for example, to diagnose conditions in other family members or if more information becomes available about the condition the person may have had.

They could also be used for medical education and audit. Medical education includes teaching and training all types of doctors, nurses and health professionals so they can provide the best care for patients in the future. Audit means checking the quality of care, procedures and tests to make sure they continue to meet the highest standards.

If the deceased had given authorisation or you give your authorisation, the medical record can be used for other purposes as well. It could be used for medical research that may benefit other patients. For example, when a new disease or health problem emerges, examining tissue on a wide scale may provide clues about how and why the disease emerged – and how to respond. This happened with the disease known as variant CJD after the BSE scare in cattle.

If any photographs could identify the person, you would be asked specifically for your permission before they could be used unless the person had authorised this use. If extra tissue or images are requested specifically for education, audit or research you would be asked to give authorisation for this separately, again unless the deceased had authorised this to be done.

What about genetic testing?

Unless the deceased or you specifically object (see section 3) if you authorise research, this will include the samples being used for medical genetic research which aims to discover the links between genes and disease. Information obtained will be anonymised so that it will not be possible to link this with the deceased's family and give this information to them unless this has been discussed with the research team before the research starts. If you should object to this, you can use section 3 of the form to say so.

How is research monitored?

All research is governed by research ethics committees which might be in the local area (research ethics committees) or that cover a number of areas (multicentre research ethics committee). Both RECs and MRECs have members of the public on the committee.

Can I find out the results of research?

You can ask if you might see the results of any research that the deceased's organs or tissue were involved in, but it may not be possible to identify an individual's contribution to a research study. The research institution will have records of its publications, and may have a website giving details of the sort of research it carries out so you should be able to obtain details of the sort of research carried out by the lead researcher and the institution.

SECTION 2: AUTHORISING RETENTION AND MEDICAL USES OF WHOLE ORGANS

Whole organs may be kept at the end of the post-mortem examination in order to carry out a more detailed examination. If this is discussed with you, there are a number of other options to consider, such as what happens to the organs afterwards.

If the deceased person left instructions authorising the gifting of organs for research, their wishes would be followed.

If the deceased did not leave instructions or you do not think he or she would have objected, you may feel that you would wish more use to be made of any organ after the Procurator Fiscal's examination is complete. There are many research studies in different areas of medicine that could benefit from a donation and a gift such as this would be appreciated and could help in research or education of future doctors. Please discuss this with the person who is explaining the post-mortem, and they should know who to ask about what can be done.

If you authorise the retention of an organ for medical education, training, audit or research it will usually not be returned and will be disposed of by the hospital or researcher once the purpose for which it has been retained has been completed.

SECTION 3: OTHER REQUESTS OR CONDITIONS

Can I make any conditions?

If you wish to make any special request or condition, please say so in Section 3. For example, there may be religious requirements that you need to have followed, or you may wish to allow some organs to be used for research but not others.

Why do I have to sign the authorisation form?

Although the post-mortem examination has been instructed by the Procurator Fiscal, the doctors need authorisation before they can use the material obtained at the post-mortem examination for medical purposes. A written record of your decision makes it clear to everyone what you have, and have not, agreed to.

How long do I have to decide?

You should take as much time as you need to make a decision. The person who is discussing the form with you should make sure you have enough information to decide if you wish to give your authorisation. They will discuss the alternatives with you. Although they may recommend a particular option, it is important that you understand and come to your own decision. They will ask you whether you have understood the information you have been given and feel able to make a decision. If you are not sure, say so.

We hope this information is helpful but please ask if there is more information you need.

AUTHORISATION FORM FOR MEDICAL USE OF MATERIAL RETAINED FROM A POST-MORTEM EXAMINATION INSTRUCTED BY THE PROCURATOR FISCAL ON A CHILD

This form and the information leaflet that goes with it are:

- to help you understand what would be involved in allowing medical education, training, audit and research to take place on material being retained from a post-mortem examination required by the Procurator Fiscal;
- to provide a record for everyone about what you want to happen if you decide to give your authorisation.

Please read the accompanying information leaflet very carefully.

It gives important general information and should be read with the leaflet provided by the Procurator Fiscal's office. **If there is anything you do not understand, or want to know more about, please ask the person who is discussing this form with you.**

If you decide to authorise medical uses of the post-mortem examination, please complete this form in discussion with the person who approached you about authorisation, and check that all the information on this form is correct. If it is, sign your name at the end of the form. The person who has discussed the examination with you will sign the form as well, and give you a copy to keep.

You should take as long as you need to think about whether you wish to authorise medical education, training, audit and research to take place as a result of the post-mortem examination.

Box for Contact Details

PAGE 1

Section 1. Authorisation of use of post-mortem examination material kept as part of the medical record.

I am the parent/guardian of _____

and I understand that the post-mortem examination required by the Procurator Fiscal involves keeping small tissue samples as blocks and slides and may involve taking photographs, X-rays and scans. I understand they will be kept as part of the medical record of my child.

I authorise them to be used for **medical education, training, audit and research.**
[See also sections 2 and 3]

PAGE 2

Section 2. Authorisation of Retention and Medical Uses of Whole Organs

You will have been told by the Fiscal whether whole organs have been retained for further examination. You will be advised if you need to complete this section. **WHOLE ORGANS WILL ONLY BE RETAINED FOR MEDICAL USES WITH YOUR AUTHORISATION.**

I authorise the use for education, training, audit and research of any whole organs removed as part of the post-mortem examination.

Section 3. Other requests or conditions

Would you like to make any other requests or conditions about the retention or future use of tissue or organs? If no, please tick box.

If yes, the person seeking authorisation should document here any special authorisations or conditions :

Signature of person witnessing authorisation

I confirm that

I have offered information to the parent(s)/guardian(s) about the procedures involved and the reasons for the medical uses of the results of the post-mortem examination requested. I have offered to explain any procedures and options available in the level of detail that the parent(s)/guardian(s) wish and have given any explanations they asked for.

If only one parent/guardian is present, I have asked whether there is likely to be objection to authorisation of medical uses of the post-mortem examination from the other parent/guardian.

I have explained that authorisation of the medical uses of the medical record cannot be withdrawn. I have explained that until the authorised research use of organs has taken place, the authorisation given by the parents/guardians can be withdrawn at any time. I have also explained how authorisation for that purpose can be withdrawn.

Information given: Leaflet Level 1 version
 Leaflet Level 2 version
 Video tape
 Other
 None

Signature of person witnessing authorisation:

Name: _____

Job title _____

Position _____

Telephone contact no _____

Bleep _____

Signature of parent(s) or guardian(s)

The medical uses of the post-mortem examination material have been explained to me and I feel I have been provided with enough information to give the authorisation set out in this form.

Name of parent/guardian (BLOCK CAPITALS) _____

Signature _____

Relationship to the child: mother/father/guardian(s) (please circle relationship)

Name of parent/guardian (BLOCK CAPITALS) _____

Signature _____

Relationship to the child: mother/father/guardian(s) (please circle relationship)

Contact Details

NOTES

1. If whole organs are not to be used for research, the relevant parts of section 2 must be scored through.
2. One copy of the completed form should be given to the parent(s)/guardian(s), one copy retained in the patient record and a copy given to the pathologist who will perform the post-mortem examination required by the Procurator Fiscal.
3. An information leaflet should also be provided to the parent(s)/guardian(s), and a note of which version of leaflet was given retained in the patient record.
4. If any part of the authorisation is withdrawn, all copies of the form should be amended with the date the authorisations are withdrawn and a clear statement who is amending the record and on what evidence, e.g. letter, telephone conversation, etc.
5. If any uses of material are envisaged which are not pre-printed on this form, separate authorisation **MUST** be obtained for these and recorded in section 3.

INFORMATION ABOUT MEDICAL USES OF A PROCURATOR FISCAL POST-MORTEM EXAMINATION OF A CHILD

SUMMARY

The post-mortem examination is an important medical examination required by the Procurator Fiscal to find the cause of your child's death. Your authorisation is not needed for this.

Your authorisation is needed for medical education, training, audit or research to be carried out on any materials obtained as a result of the post-mortem examination.

Ideally the post-mortem examination should take place within a day or two of death.

Whole organs are sometimes kept to assist the diagnostic examination. They will only be kept for other medical uses if you authorise this.

Ask as many questions as you wish.

INFORMATION ABOUT MEDICAL USES OF MATERIAL OBTAINED AT A CHILD'S PROCURATOR FISCAL POST-MORTEM EXAMINATION

We understand that this is a very difficult time for you and it may be hard to consider medical uses of the post-mortem examination required by the Procurator Fiscal. This leaflet has been written to give you clear information about the reasons why you might wish to consider authorising medical uses of material obtained from the post-mortem examination, and what you would need to decide.

The post-mortem examination

Following the death of your child, it will have been explained to you that the Procurator Fiscal has decided that a post-mortem examination needs to be carried out. The post-mortem examination, and the tests which are later performed in the laboratory, are undertaken to find the cause of death. Your authorisation is not needed for this to happen. However we do need your authorisation if we are to do further studies to learn more about the condition which caused the death of your child. This leaflet tells you about the possibilities for helping with this kind of medical education, audit, training and research, and tries to answer some of the questions you may have.

The following notes refer to the sections in the authorisation form for medical uses of the post-mortem examination material.

What do I need to know?

People have different views on how much information they want about the post-mortem examination itself and the possible medical uses of a post-mortem examination. You should ask as many questions and read as much information as you want.

You may not want to know any more about the post-mortem examination itself but would nonetheless be willing to help. Even if you do not wish to know more about the post-mortem examination, you may want to be told more about the kind of research which might be carried out. If, on the other hand, you would like more detail or would like to discuss it with another health professional (such as a pathologist), please ask.

Section 1: Authorisation for using post-mortem examination material kept as part of the medical record.

Small tissue blocks and slides, photographs and X-rays are made as part of the post-mortem examination.

What are tissue samples, blocks and slides?

Although some information can be obtained from looking directly at organs and tissues in a post-mortem examination, often the only way to understand properly what has happened is to look at small tissue samples under the microscope. These samples are very small, slightly thicker but usually no larger than a standard postage stamp. These tissue samples are chemically treated to remove water which is replaced by wax. This produces a tissue block from which a very thin section (ten times thinner than a human hair) can be cut. It is mounted on a glass slide before being stained. A very large number of sections can be cut from one tissue block, and a number of different stains can be used to show different features. (For more detailed information, please ask.)

Using post-mortem examination material kept as part of my child's medical record?

Once the post-mortem examination instructed by the Procurator Fiscal has been completed, the tissue samples, blocks and slides, and any records made as part of the post-mortem examination, will become part of your child's medical record. However, they cannot be used for any purposes other than those related to the Procurator Fiscal's investigation of the death unless appropriate authorisation has been given.

Using the material as part of the child's medical record may be useful for the family in future, for example, to diagnose conditions in other family members or if more information becomes available about the condition the child may have had. They could also be used for medical education and audit. Medical education includes teaching and training all types of doctors, nurses and health professionals so they can provide the best care for patients in the future. Audit means checking the quality of care, procedures and tests to make sure they continue to meet the highest standards.

If you give your authorisation the medical record can be used for other purposes as well. It could be used for medical research that may benefit other patients. For example, when a new disease or health problem emerges, examining tissue on a wide scale may provide clues about how and why the disease emerged, and how to respond. This happened with the disease known as variant CJD after the BSE scare in cattle.

Once you have agreed to the medical record obtained at post-mortem examination being used for medical education, training and audit, this

authorisation cannot be withdrawn. However, if you change your mind about donating material for medical research before the materials have been used for such research you can withdraw your authorisation, even after signing. If any photographs could identify your child, you would be asked specifically for your permission before they could be used in published research. If extra tissue or images are requested specifically for education, audit or research, you would be asked to give separate authorisation for this.

What about genetic testing?

If you authorise research, this will include the samples being used for medical genetic research which aims to discover the links between genes and disease. Information obtained will be anonymised so that it will not be possible to link this with you or your family and give this information to you unless this has been discussed with the research team before the research starts. If you would object to genetic research, you can record that objection in section 3.

How is research monitored?

All research is governed by research ethics committees which might be in the local area (research ethics committees) or that cover a number of areas (multicentre research ethics committee). Both RECs and MRECs have members of the public on the committee.

Can I find out the results of research?

You can ask if you might see the results of any research that your child's organs or tissue were involved in, but it may not be possible to identify an individual's contribution to a research study. The research institution will have records of its publications, and may have a website giving details of the sort of research it carries out so you should be able to obtain details of the sort of research carried out by the lead researcher and the institution.

Section 2: Authorising retention and medical uses of whole organs

Whole organs may be kept at the end of the post-mortem examination in order to carry out a more detailed examination. If this is discussed with you, there are a number of other options to consider, such as what happens to the organs afterwards.

You may feel that you would wish more use to be made of any organ after the Procurator Fiscal's examination is complete. There are many research studies in different areas of medicine that could benefit from a donation and a gift such as this would be appreciated and could help in research or education of future doctors. Please discuss this with the person who is explaining the post-mortem, and they should know who to ask about what can be done.

If you authorise the retention of an organ for medical education, training, audit or research it will usually not be returned and will be disposed of by the hospital or researcher once the purpose for which it has been retained has been completed.

Section 3: Other requests or conditions

Can I make any conditions?

If you wish to make any special request or condition, please say so in Section 3. For example, there may be religious requirements that you need to have followed, or you may wish to allow some organs to be used for research but not others.

Why do I have to sign the authorisation form?

Although the post-mortem examination has been ordered by the Procurator Fiscal, the doctors need your authorisation before they can use the material obtained at the post-mortem examination for medical purposes. A written record of your decision makes it clear to everyone what you have, and have not, agreed to.

How long do I have to decide?

You should take as much time as you need to make a decision. The person discussing the form with you should make sure you have enough information to decide if you wish to give your authorisation. They will discuss the alternatives with you. Although they may recommend a particular option, it is important that you understand and come to your own decision. You will be asked whether you have understood the information you have been given and feel able to make a decision. If you are not sure, say so.

We hope this information is helpful but please ask if there is more information you need.

AUTHORISATION LEAFLETS AND FORMS FOR HOSPITAL POST-MORTEM EXAMINATIONS: A GUIDE FOR HEALTH PROFESSIONALS

Introduction

The death of a relative can be a difficult time for the health professionals involved, as well as relatives. Asking relatives to authorise a hospital post-mortem examination is a delicate and challenging task and is one of the most difficult interviews that staff have to face. However, experience shows that a sensitively handled, well informed discussion does not need to be distressing.

Before discussion with relatives, the professional should ensure they know:

- **Whether the death must be reported to the Procurator Fiscal (see Appendix to this leaflet)**
- **Why they think it would be helpful to carry out a post-mortem examination**
- **Where the examination would take place**
- **Local practices**
- **Possible outcomes and when the results will be available**
- **Where to locate the NHS QIS standards on hospital post-mortem examinations.**

Relatives vary in their requirement for information, and they should be given the opportunity to say if they do not wish certain information. There are two versions of the information booklet. The first information leaflet should be offered to all relatives, although they may decline it, while the second is designed for those who require more detailed information.

Scope

Hospital post-mortem examinations are currently carried out under the Human Tissue Act 1961. Many people feel that this does not meet today's requirements, and it is likely to change. It seeks to establish that the deceased had no objection to a post-mortem examination and no relative has an objection. This Act does not deal with body parts or organs held under the Anatomy Act 1984. If the deceased wished their body to be donated to medical science, this should have been arranged with a medical school before death. Retrieval of organs for transplantation is also the subject of a separate process.

Mature child

In Scotland, children are given statutory authority to make all medical decisions for themselves at the age of sixteen and from that age would be treated in law as adults. Below that age, children may be considered to be able to make medical decisions for themselves. Whether they are able to do so depends on their individual ability to consider the issues involved. It may be unusual for a child or young person to have considered what they would want to happen to their bodies after death, and in particular whether they would wish to authorise a post-mortem examination or the retention of organs. Where, for example, children have had a long or a serious illness, they may have views on the matter. If the member of staff primarily responsible for the care of the child believes he or she is capable of considering the issues involved, and the child wishes to express views, these should be carefully recorded on the child's medical notes and, where possible, signed by the child, dated and witnessed. In the event of the child's death, the views of the mature child would take precedence over the views of the parents, if they differed. In such cases, if the child authorised the post-mortem examination and/or the retention of organs this could proceed even if parents objected. Similarly, if the child had objected, parents could not override this refusal of authorisation. Clearly this is an issue of very great sensitivity and, where possible, discussions should involve the whole family so that parents are aware of the child's views while the child is still alive.

Fetus

Where a post-mortem examination is to be carried out on a fetus, authorisation needs to be obtained from the mother (see the 1989 Polkinghorne Report). But it is good practice to also obtain authorisation from the father if possible, although the mother would need to give her permission for him to be contacted.

Reasons for Post-mortem examination

The post-mortem examination is crucially important in informing relatives, clinicians and legal authorities about the cause of death, and in telling those bereaved families, who wish to know, about the possibility of acquired and genetic diseases which might need care and treatment. More widely, it is important in improving clinical care, maintaining clinical standards, increasing our understanding of disease, preventing the spread of infectious diseases, and in supporting clinical research and training.

The reasons may be summarised:

- It may provide confirmation of the clinical diagnosis
- It may provide a cause of death
- It may give information on implications of treatment
- It is a form of medical audit
- It may exclude or diagnose an inherited disease

Post-mortem examinations have been shown to reveal unexpected findings that would have affected treatment and might have affected outcome in 10–15% of cases. This is the case whether clinical staff are sure of the cause of death or whether modern scans have been carried out in life.

The Fiscal post-mortem examination

The Procurator Fiscal has a legal duty under common law to investigate deaths in a number of circumstances. Informing the Fiscal does not automatically mean a post-mortem examination will take place. Any discussion with the Procurator Fiscal **MUST** take place before any discussion with the relatives. **The Procurator Fiscal system should never be used to circumvent the relatives' refusal to authorise a hospital post-mortem examination.**

See Appendix 2 for categories of death that must be reported to the Procurator Fiscal.

Following a Fiscal post-mortem examination, if relatives wish to authorise the use of tissue blocks and slides or organs for research or teaching, a specific authorisation form must be completed. It is based as closely as possible on the hospital post-mortem examination authorisation forms.

Transport of bodies for post-mortem examination

If post-mortems are centralised to a hospital in your area, then the body may have to be moved for the examination. This is carried out by an undertaker; relatives should always be informed of the need for this transfer. You may need to contact the pathology department to clarify details about how long this may take.

Timing of the post-mortem examination

It is advantageous to perform a post-mortem examination as soon as possible after the death (usually within 1 or 2 days). Delays may affect the quality of some results such as bacteriology, but relatives should be given as much time as they need to make their decision.

The post-mortem examination

All post-mortem requests to the pathologist should include a written clinical summary and a copy of the authorisation form. The case notes are also required by the pathologist to allow the examination to be put in its clinical context. It is best practice to leave catheters and drains, etc, in situ.

There are usually two incisions, one from the neck to the pubic bone, and a second over the back of the head to examine the brain. After the body is restored and the deceased is suitably dressed, these incisions should not be visible. A pathologist, assisted by a technician performs a post-mortem examination with the care and respect that would be exercised during a surgical operation.

If medical students are to view the post-mortem examination as part of their training, this should be explained to the next of kin.

Limited post-mortem examinations

Some relatives may be reluctant to give consent for a full post-mortem examination. There are circumstances where a limited post-mortem may be of value, especially if it is directed at answering specific questions. Incisions can be more limited and even recent surgical operation incisions can be used if appropriate. Needle biopsies may provide useful information in some cases, for example a liver tumour or lung mass. Where a limited examination is being considered, discussion with a pathologist is advisable to make sure the relative's wishes are adhered to, and whether the suggested examination is going to answer the clinical questions.

If the pathologist feels that the limitations placed on the post-mortem examination make the value questionable or make it difficult for him/her to carry out a post-mortem to a professional standard, he/she may advise the family that the investigation should not be carried out.

Feedback to relatives

Relatives usually want to know when they will have the results of the post-mortem examination and other tests. The initial report will be issued in 2 days, and the final report in 21 days. Where specialised tests are performed such as neuropathology or genetics, results may take up to 3 months. (See the NHS Quality Improvement Scotland Standards for post-mortem examinations.)

Final reports are sent to the consultant in charge and the deceased's general practitioner with whom the results can be discussed. Relatives are entitled to see and to have a copy of the post-mortem report. This is best done during an interview, when medical terminology can be explained.

Images

Photographs and X-rays may be taken as part of a post-mortem examination, these form part of the medical record and the uses of this together with the tissue blocks and slides are governed by Section 1 of the authorisation form. All uses will be governed by the GMC rules on patient confidentiality, and the use of images that are identifiable will need specific authorisation for their use.

Tissue samples

Post-mortem examinations require a range of tissue samples to be taken for histological examination, and sometimes for bacteriology and/or virology. Those for histology will be processed and converted to tissue blocks and embedded in paraffin in the same way as surgical biopsies are treated, they will be stored safely and securely for at least 30 years. These tissue blocks and the glass slides produced from them are regarded as part of the medical record of the deceased.

If relatives have authorised it, these tissue samples taken for diagnosis may be used for medical education and audit in the future. This will not destroy the tissue but will allow training of future doctors and healthcare staff. This use is covered in Section 1 of the authorisation form. Any use would be governed by the GMC rules on patient confidentiality.

It might also be that these samples could be used for research in the future; this might mean anything from a single further section to a series of sections to look at specific genes. Again, the relatives should indicate their authorisation in Section 1. Any research that would be carried out on this material would have to be approved by a Research Ethics Committee.

If any additional material was required either for audit, research or teaching, there would have to be specific consent given by the relatives using a different consent form.

Organ retention

In some circumstances it is good practice to retain a whole organ for later detailed examination. This is most commonly the brain or heart. The brain is extremely soft and requires a prolonged period of fixation (usually 4-6 weeks) before being serially sectioned and examined, usually by a neuropathologist who may not be in the same hospital as the post-mortem examination itself. It may be possible to make a more rapid examination of the brain so that it can be returned to the body before the funeral, and discussion should take place with the pathology department (see below). The heart may have

complex congenital heart disease, or a previous operation, or it may require examination of the conducting system, and it may need to be carried out by a specialist in a different hospital.

It is necessary to obtain specific authorisation for the retention and examination of a whole organ. While this may seem difficult, experience has shown that relatives will often authorise this if they are provided with a full explanation as to its necessity. Extreme distress has been caused in the past by organs having been retained without the knowledge of the relatives.

If a whole organ is to be retained, there should be some discussion with the relatives as to the intended method of disposal after the examination. The pathology department should be contacted if there is a possibility of an organ being retained, and the various options for disposal discussed with them and with the relatives. The length of time required for the examination of the organ may be able to be modified to allow the organ to be returned to the body before the funeral. This **MUST** be discussed with the pathology department. The Cremation (Scotland) Amendment Regulations 2003 now allow cremation of body parts retained from a post-mortem examination.

Quality standards

The Royal College of Pathologists have published guidelines concerning post-mortem examinations, and the NHS Quality Improvement Scotland have published standards which hospitals and pathology departments must adhere to, regarding the authorisation process and the information from a post-mortem examination.

Viewing the deceased

Routine Cases: viewing and handling the body by relatives is now considered good practice to aid the grieving process.

High Risk Cases: Viewing and handling the body before the post-mortem is acceptable with similar restrictions to those during life. After the post-mortem, the body will be within a sealed bag, and handling should be discouraged because of the risk of spreading infection. Where it is believed that a body may be a high risk case the implications of this should be explained to the relatives beforehand.

All Cases: Bodies are restored after post-mortem examination so that, with appropriate clothing, the deceased can be seen by their relatives.

Requesting the pathologist to undertake the post-mortem examination

All requests to the pathologist to carry out a post-mortem examination must include a correctly completed authorisation form with full patient identification and a brief clinical summary including the questions to be answered from the examination.

For a child, authorisation must be sought from those with parental responsibility.

It is always best, where both parents are available that they agree on whether or not a post-mortem examination can be done. Where only one parent is available at the hospital, he or she should be asked if they think the other parent would object. The other parent may not be involved with the care of the child and the post-mortem examination can go ahead if only one parent authorises it. However, if the other parent objects or would be likely to object, then usually the post-mortem examination would not be done. There may be unusual circumstances in which parents disagree strongly over whether a post-mortem examination should be done. In such cases, there may be a need for this to be resolved through informal means (such as discussion) or in exceptional cases formal means (with legal advice).

If the child was in care, the local authority may have parental authority. However even where the natural parents do not have that responsibility, they might reasonably expect to be consulted and, save in exceptional circumstances, where either parent objects the post-mortem examination should not proceed.

For an adult, or a mature child, the deceased's wishes are paramount and override the wishes of the relatives. Adults or mature children who want to make decisions about what should happen to their bodies after death should have their wishes about post-mortem examination and organ retention recorded in their medical notes. Where possible this should be signed by the patient, dated and witnessed. In the event of the adult or mature child's death the medical records should be checked for any information about the deceased's wishes and these should be followed.

Where there is no note in the medical records of the adult's wishes about post-mortem examination or organ retention, the relatives should be asked if they know if the deceased had made any particular request. Contemporary families may have complex relationships and identifying the most appropriate person to give authorisation may be difficult. In order to simplify this, all

competent adults should be asked to nominate a next of kin or representative on admission to hospital. It should be explained that this person will be consulted in the event of information being needed about the individual's likely wishes if he or she is not able to be asked for him or herself. This would include, for example, treatment decisions in the case of incapacity as well as decisions about post-mortem examination.

If there is no nominated individual, and the deceased is not known to have had any objection to post-mortem examination then authorization for post-mortem examination can be sought from the deceased's next of kin. In the absence of nomination, the next of kin will need to be determined by the hierarchy established in the Adults with Incapacity (Scotland) Act 2000 and the Mental Health (Care & Treatment) (Scotland) Act 2003, which is broadly as follows:

- a. spouse (please see below)
- b. child
- c. father or mother
- d. brother or sister
- e. grandparent
- f. grandchild
- g. uncle or aunt
- h. nephew or niece

For details of how the hierarchy is established, see the relevant statutes. However, it should be noted that a spouse includes a person with whom the deceased lived as if he or she were the husband or wife of the deceased for at least 6 months. A spouse also includes a partner of the same sex as the deceased with whom the deceased lived in a relationship for at least 6 months which has the characteristics of husband and wife, other than that the persons are of the same sex. It does not include spouses who are divorced from the deceased or permanently separated or where there has continuing desertion.

Sections 1 of the authorisation form must be completed in **all** cases.

Section 2 does not need to be completed unless whole organs are to be retained after the examination. If it does not need to be completed it should be scored through before the relative signs the form.

Section 3 should be used if there are any particular religious or practical details that the relatives wish to make known.

After signing, the completed authorisation form should be split into **three** parts, **one** to the relatives, **one** for the pathologist and **one** copy to be inserted in the case notes.

Authorisation

Relatives vary in their desire for information, and must be given sufficient time to reach a decision. If they do not wish to know details of the post-mortem examination, their wishes must be respected. A few may wish to know every detail, and there is a second booklet with much more detail about the post-mortem examination available.

The way in which pathological investigation is discussed with the family is very important, they need to be given:

- Honest, clear objective information.
- The opportunity to talk to someone they trust and of whom they can ask questions, if necessary they should be able to speak to a pathologist.
- Reasonable time to reach a decision.
- Privacy to discuss matters between family members in a suitable environment.
- Support if they need it and want it, including the possibility of further advice or bereavement counselling or psychological support.

The person who obtains authorisation for a hospital post-mortem examination should, wherever possible, be a consultant. He or she must be sufficiently senior and well informed and have knowledge of the procedure. Often there will be a team approach and nurses and midwives will be in a good position to have built a rapport with relatives and parents to help answer questions they may have.

Cultural beliefs

Attitudes to death, post-mortem examination and the use of organs and tissues after death vary greatly, the individual designated to provide bereavement support must be fully informed about the values and beliefs of a wide range of cultures and religions, particularly those of the local community. However all healthcare professionals need to be aware of these values and respond to them sensitively. Trusts must ensure that there is adequate training of all staff who are likely to deal with bereaved relatives.

APPENDIX 2

Categories of death that must be reported to the Procurator Fiscal:

- (1) any uncertified death;
- (2) any death caused by an accident arising out of the use of a vehicle including an aircraft, a ship or a train;
- (3) any death of a person while at work;
- (4) any death resulting from an accident in the course of work or arising out of industrial disease or poisoning;
- (5) any death due to poisoning;
- (6) any death where the circumstances indicate that suicide may be a possibility;
- (7) any death where there are indications that it occurred as a result of medical mishap;
- (8) any death resulting from an accident;
- (9) any death following an abortion or attempted abortion;
- (10) any death where the circumstances seem to indicate fault or neglect on the part of another person;
- (11) any death occurring while the deceased was in legal custody as defined in section 1(4) of the Fatal Accidents and Sudden Deaths Enquiry (Scotland) Act 1976;
- (12) any death of a new born child whose body is found;
- (13) any death (not occurring in a house) where a deceased's residence is unknown;
- (14) any death by drowning;
- (15) any death of a child from suffocation including overlaying;
- (16) any death which may be categorised as due to sudden death in infancy syndrome or sudden unexplained death in infancy (SUDI). The term sudden unexplained death in infancy (SUDI) is now used by many paediatricians in preference to SIDS (sudden infant death syndrome). This terminology recognises that the mechanism for such deaths is not fully understood and that there may be a number of causes which are not attributable to a single syndrome.

- (17) any death occurring as a result of food poisoning or an infectious disease;
- (18) any death by burning or scalding or as a result of a fire or explosion;
- (19) any death of a foster child;
- (20) any death of a child in the care of a local authority;
- (21) any death of a child on a local authority "At Risk" register;
- (22) any drug related death;
- (23) any death, if not already reported, where a complaint from the next of kin is received by a Health Board or NHS Trust and the complaint is about the medical treatment given to the deceased with a suggestion that the medical treatment may have contributed to the death of the patient;
- (24) any death which occurred in a GP's surgery, Health Centre or similar facility;
- (25) any other death due to violent, suspicious or unexplained cause.

1. INDUSTRIAL DISEASES OF THE LUNGS

Anthracosilicosis Anthracosis
 Asbestosis
 Bagassosis
 Berylliosis
 Byssinosis
 Chemical pneumonitis
 Dust reticulation
 Extrinsic allergic alveolitis
 Occupational asthma
 Pneumoconiosis
 Siderosis
 Silicosis
 Any lung disease qualified by an occupational term (eg grinder's phthisis, farmer's lung)

2. ZOO NOTIC DISEASES

(diseases transmitted from animals to man)

Brucellosis
 Hydatid disease
 Ornithosis
 Psittacosis
 Erysipeloid (of Rosenbach)
 Contagious ecthyma (Orf)

3. OTHER INDUSTRIAL DISEASES

(except poisonings covered by item 4)

Angiosarcoma
 Anthrax
 Caisson disease
 Compressed air sickness
 Decompression sickness
 Diver's palsy
 Dysbarism
 Hyperbarism
 Leptospirosis
 Malignant pustule
 Mesothelioma
 Spirochaetal jaundice
 Weil's disease

Malignant disease (cancer or sarcoma), leukaemia, anaemia or blood dyscrasia if attributed on the medical certificate of cause of death to X-rays or radioactive substances or radiation.

Any form of cancer if shown to be of industrial origin or due to specified substance. Such as:

Cancer of the skin (epitheliomatous ulceration, epithelioma, squamous-celled carcinoma) due to tar, mineral oil, arsenic pitch, bitumen, soot etc. Cancer of the nose (nasopharynx, nasal sinuses) or of the lung (bronchus or bronchial) if shown to be due to nickel fumes or vapour or associated with wood or leather working.

Cancer of the bladder or renal pelvis or ureter (papilloma of the bladder) if due to industrial chemical or dye-stuff preparations or processes.

Hepatitis B, viral hepatitis, hepatitis caused by Australia antigen, serum hepatitis and any form of hepatitis where the deceased was a medical or dental worker.

Any other disease qualified by an occupational term (eg wool-sorter's disease).

4. INDUSTRIAL POISONING

Toxic jaundice or toxic anaemia (unless the medical certificate clearly indicates that the condition is due to natural causes.)

Plumbism

Saturnism

Any condition certified as "... poisoning or poisoning by ..."

NOTIFIABLE INFECTIOUS DISEASES

Anthrax

Bacillary Dysentery

Chickenpox

Diphtheria

Erysipelas

Food Poisoning

Legionellosis

Leptospirosis

Lyme Disease

Malaria

Measles

Membranous Croup

Meningococcal Infection

Mumps
Paratyphoid Fever
Plague
Poliomyelitis
Rabies (hydrophobia)
Rubella
Scarlet fever
Smallpox
Tetanus
Toxoplasmosis
Tuberculosis
Viral Haemorrhagic Fever, (including Yellow Fever, Lassa Fever
and Marburg Disease)
Viral hepatitis
Whooping cough
Fevers known by any of the following names: typhus, typhoid, enteric
relapsing continued or puerperal.

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