

Appendix 10

**Royal College of Pathologists:
Guidelines for the retention of tissues
and organs at post-mortem examination
(March 2000)**



The Royal College of Pathologists



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tissues and organs
at post-mortem examination**

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Further copies of this booklet (along with Annex A which is available as a separate leaflet) are available from:

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Introduction

1.1 These guidelines on the retention of tissue and organs at post-mortem examinations are intended to help all doctors, particularly pathologists, and Coroners, Procurators Fiscal and their staff make decisions about this sensitive issue, and thereby to ensure that the examination of the body after death continues to have public support and is conducted in a respectful manner in which the public has confidence. These guidelines apply only to the retention of tissues and organs from post-mortem examinations rather than from biopsies or surgical resections. The main relevant legislation is the Human Tissue Act 1961,¹ but these guidelines seek to address not only the law but also the ethical and emotional concerns of bereaved relatives, thus representing a statement of good practice to inform and reassure the public.

1.2 The Royal College of Pathologists promotes and maintains high standards of post-mortem examinations, and this includes a requirement to ensure that the bereaved are treated with respect.

1.3 Despite modern advances in the investigation and management of patients, post-mortem examinations continue to serve the public by providing information leading to advances in the practice of clinical medicine. Surveys continue to show significant discrepancies between ante-mortem clinical diagnoses and the actual cause of death determined by postmortem examination. New diseases are still being recognised and characterised in tissues obtained during post-mortem examinations - for example, variant Creutzfeldt-Jakob disease. New imaging techniques have not superseded the traditional post-mortem examination, but are evaluated against post-mortem examination as the 'gold standard'. Post-mortem examinations also enable:

- information and explanations to be provided to bereaved families and their doctors
- audit of new and established medical,

surgical and investigative procedures and their complications

- audit of disease treatment, particularly the effects of new or trial therapies and the discovery of unexpected complications
- histological study of diseases and the benefits or adverse effects of treatment
- accurate mortality and morbidity statistics
- the legal investigation of accidental, unnatural, suspicious and clinically unexplained deaths
- teaching and training of medical students, doctors and other health-care personnel.

1.4 In most cases, the post-mortem examination involves the retention of tissue samples or fluids for laboratory examination and, in some cases, there will be a need also to retain one or more whole organs for further examination in order to verify the cause of death and to study the effects of treatment. To ensure that the retention, examination and disposal of tissues and organs is acceptable, the views and feelings of relatives² must be respected. The opportunity for pathologists to perform post-mortem examination is qualified also by legal and ethical constraints. Unfortunately, the interpretation of the law surrounding post-mortem examination is often not entirely clear.

Also, in a multicultural society, the public's attitudes to the human body after death and its understanding of 'informed consent'³ are constantly changing. Society's attitudes to death and to the care of the human body after death has evolved with time, partly reflecting cultural diversity. At the same time, the public and patients no longer wish important decisions to be taken by professional staff on their behalf, but expect a full informed partnership in all such decisions. Relatives therefore need to be given information by people they trust, so that they can understand the implications of decisions and be assured that due account is taken of their wishes.

1.5 The post-mortem examination is not just the external and internal examination of

¹ The relevant passage reads: "...the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe: (a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or (b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with." The "said purposes" are earlier defined as "therapeutic purposes or for the purposes of medical education or research".

² In these guidelines, "relatives" are defined as the spouse or other surviving relatives (a spouse is not in law a relative, except where the spouse is also a cousin or otherwise related). However, it should be noted that, in the UK, over 40% of relationships are outside the legal framework of marriage; this important shift in social mores is not catered for by the Human Tissue Act 1961.

³ The concept of "consent" is problematic and its use does not reflect what is laid down in law in the Human Tissue Act 1961. The difficulty is amplified when phrases such as "informed consent" or "fully informed consent" are used. These guidelines do not subsequently refer to "consent", but use the term "agreement" to infer that a relative "does not object" as provided for by the HTA 1961.

the body, but includes histological or other laboratory examination of retained tissues. Thus, in many cases, the value of the post-mortem examination would be curtailed and important information lost if the opportunity to retain tissue were denied. Histological examination also enables audit of the reliability of gross interpretations of post-mortem findings and any tissue preserved, for example in paraffin wax blocks, provides a permanent archive of the case which may assist further clinical enquiries about the deceased's illness.

1.5 The need to retain a whole organ occurs most commonly in the post-mortem investigation of disorders of the nervous system; in such cases, the brain and/or spinal cord should be retained for further examination after fixation. The diagnosis of many diseases of the brain requires specialised investigations which are not available in many hospitals; consequently, the brain may have to be sent to a specialist laboratory.

Occasionally complete examination of the heart may require its retention. The need to retain an eye or eyes is not common. Relatives must be reassured that aesthetically acceptable reconstitution of the body will be undertaken in all cases.

1.7 Relatives' attitudes to organ retention may vary according to:

- their regard for the medical benefits of examining the body after death
- the age of the deceased and proximity of the relationship
- the circumstances and cause of death
- the symbolic, religious and cultural significance of individual organs and of the body as a whole.

Recent experience shows that there are particular sensitivities about parents agreeing to or, in examinations directed by law, being informed about post-mortem examinations and the retention of tissues or organs from a fetus, baby or young child. Also, in these cases, the post-mortem examination (with possible retention of tissues or organs) can be important in informing the prognosis and, therefore, parents' decisions about future pregnancies.

1.3 Relatives' views need not be taken into account if, in accordance with Section 1(1) of the HTA 1961, the deceased made a lifetime request for their body or tissues to be used

for transplantation or for medical education or research.

1.9 Relatives and the public generally need to be better informed about how post-mortem examinations lead to improved medical practice. The falling clinical post-mortem examination rate impacts adversely upon clinical audit and impedes the accountability of the medical profession to the public. Satisfactory rates should be an integral component of a hospital's clinical governance strategy, but without putting undue pressure on relatives to serve this purpose.

1.10 Doctors who provide information and seek the agreement of relatives must emphasise the benefits of post-mortem examinations in enabling a fuller understanding of the deceased's illness and the possibility that medical knowledge may be advanced for the benefit of future patients. This applies to the post-mortem examination itself and to the retention of any tissues or organs from it. In seeking agreement for a post-mortem examination (full or limited) or the retention of tissue of organs, there is a duty to provide all relevant information to relatives which might influence their decision; in some cases this may include knowledge that the post-mortem examination and any retention of tissue of organs may be helpful in resolving later issues relating to the severity or extent of disease or its management.

Legal and ethical principles

2.1 The following principles apply to the retention of tissues:

- Retention of tissue must be lawful, i.e. must not contravene statute or breach a common law tenet (e.g. obscene display).
- Reasons for the retention of tissue must be defensible, open, and justifiable in law and in clinical practice.
- Unless the post-mortem examination is directed by law,⁴ the procedures must be sufficiently flexible to reflect the wishes of relatives, while maintaining standards of diagnostic accuracy.
- If the post-mortem examination is directed by law, where possible and practicable the relatives should be fully informed before the examination of what is to be done and its purpose.

⁴ Post-mortem examinations directed or requested by the Coroner or, in Scotland, the Procurator Fiscal.

Taking into consideration these principles, these guidelines seek to ensure that the retention of tissues and organs at post-mortem examination complies with relevant legislation and is professionally regulated to high ethical standards.

2.2 It is unlawful for a pathologist to perform a post-mortem examination or retain any tissue, regardless of the amount, without proper authorisation. Although the retention of very small amounts of tissue, e.g. for histology, may not seem to warrant agreement or authority, this retention is no less susceptible to the need for proper authorisation than the retention of larger specimens or whole organs.

2.3 Different conditions apply to hospital postmortem examinations carried out with the agreement of relatives and post-mortem examinations directed or requested by a Coroner or Procurator Fiscal. The latter examinations constitute the majority in the UK.

2.4 The process of retention of material from postmortem examinations requires clarification and explanation in individual cases in respect of:

- the primary purpose of retention, whether it be for verifying the investigating the cause of death or for teaching, training or research;
- the type of material to be retained, whether it be tissue samples or whole organs;
- the duration of the period of retention;
- the mode of disposal of retained material.

Post-mortem examinations required by law

Arrangements in England, Wales and Northern Ireland: Coroner's post-mortem examinations

3.1 If a pathologist has reason to believe that an inquest may be required to be held on any body or that a Coroner may direct or request post-mortem examination of a body, then the Human Tissue Act (1961) prevents the

pathologist proceeding with an examination, even where the relatives have agreed, without permission of the Coroner.

3.2 Coroners may empower pathologists to carry out only such investigations as are necessary to establish how and why the deceased died, particularly if such investigations remove the necessity for an inquest.⁵ Therefore, the purpose of a Coroner's autopsy is to ascertain the medical cause of death having investigated and taken into account the impact of all pathological findings. Coroners cannot sanction removal of tissue except as allowed under the Coroner's Rules. A Coroner's post-mortem examination must not be used as a pretext to obtain tissue for research unrelated to these matters, and to do so without proper authorisation contravenes the Human Tissue Act.

3.3 Coroner's pathologists may retain tissues as follows:

"A person making a post-mortem examination shall make provision, so far as possible, for the preservation of material which in his opinion bears upon the cause of death, for such a period as the Coroner thinks fit"
(Rule 9, Coroner's Rules, 1984)

In every case where this issue arises, the pathologist must seek the Coroner's view as to the period of retention. The Coroner may well enquire as to the amount of tissue, the time over which the tissue is likely to be needed (this may be important if a whole organ is to be reunited with the body before disposal) and the expected outcome of any tests. This is not without difficulty and each case will have to be considered carefully. In certain circumstances, however, it is clear in advance of the examination that large tissue samples, or even complete organs, should be retained until no longer needed in connection with the post-mortem examination.⁶

3.4 Some Coroners will allow tissue retention only if they have opened an inquest, while others allow it if pathologists indicate in their reports that further investigations are being undertaken which may alter the cause of death.

⁵ Coroners may authorise a post-mortem examination on a body within their jurisdiction. This examination should be made by a pathologist with suitable qualifications and experience, with access to laboratory facilities. In England and Wales, this authority is granted by the Coroners' Act (1988) and regulated by the Coroners' Rules (1984). In Northern Ireland, authority is granted by the Coroners Act (Northern Ireland) 1959 (Amended 1977) and regulated by the Coroners Rules & Regulations (Northern Ireland) 1963 (Amended 1977) Rule 30.

⁶ Examples include the most affected lung and pleura in a patient who has died with malignant mesothelioma, or the whole brain in a patient in whom Creutzfeldt-Jakob disease was suspected clinically. The whole brain should be preserved in cases of suspected encephalitis or unexplained encephalopathy. The precise cause of a dementia or neurodegenerative disease commonly bears directly on the cause of death and establishing this usually requires retaining the whole brain for histological examination after fixation; when this is not possible, preserving samples for histology from multiple key areas should be a minimally acceptable alternative.

3.5 Post-mortem examinations required by law are often performed in circumstances where the pathologist has a minimal amount of information relating to the medical aspects of the case; this information may emerge only after the examination has been completed. Most Coroners allow their pathologists considerable discretion in the way in which they carry out their examinations. Pathologists must strive to ensure that procedures in a Coroner's autopsy conform to a high medical standard including the routine preservation of samples from major organs for histopathological examination, unless it is known that there are objections or that retention has been disallowed by the Coroner; in such cases, the limitations of the examination must be stated in the written report. Therefore, it is recommended that:

- a) Pathologists performing post-mortem examinations at the request of a Coroner should have clear protocols agreed with that Coroner pertaining to the retention of tissues.
- b) Coroner's autopsy reports should state when whole organs have been retained, and the reasons given in the report. However, disclosure arrangements will need to be discussed with local Coroners who may themselves wish to review their approach in the light of these guidelines. Coroners should inform relatives and advise them of the date when the organ(s) may be released. However, if the relatives declare that they wish to have the organ(s) cremated or reunited with the body after burial, Coroners should make it clear this would be the relatives' responsibility. Most Coroners will release organs only to a funeral director chosen by the relatives.
- c) If retention of tissues or organs not within the remit of the Coroner's post-mortem examination appears desirable, the agreement of relatives should be obtained in accordance with the HTA 1961. The Coroner's authorisation must also be sought; it is only where there are good grounds for refusal that the Coroner's authorisation is likely to be withheld.
Coroners may forbid such extra samples to be taken even when the relatives agree, but cannot authorise them

without their agreement.

3.6 There will be rare occasions when, during the course of a Coroner's post-mortem examination a pathologist discovers a condition which has no bearing on the cause of death, but believes it should be investigated further in the best interests of the deceased's family. For example, post-mortem examination may reveal a possible hereditary disorder incidental to the cause of death, but with implications for other family members. In these circumstances appropriate samples should be retained, unless there are known to be particular religious or cultural reasons why this should not be done, and testing deferred until relatives have been informed of the possible outcomes and given their agreement. If the relatives do not agree to the retention and further examination of the tissue, it must be returned to the body.

3.7 In terms of criminal proceedings, the Crown Prosecution Service advises that the pathologist who appears for the prosecution, and who tends to have examined the body before the defence pathologist, must retain and make available relevant material for the latter; failure to do so may result in the proceedings being stayed. The issue as to the length of retention is still unclear. The Code of Practice⁷ issued pursuant to the Criminal Procedure and Investigation Act 1996 provides for the following minimum retention periods for relevant material:

- a) three years in respect of a conviction after a not guilty plea at a trial on indictment;
- b) if an appeal is lodged, until after the appeal is determined.

3.8 Where civil litigation is in prospect, relatives should be advised urgently to seek legal advice which would include a recommendation as to whether it would be desirable to retain certain tissues or organs. If there is any possibility of legal action on behalf of the deceased's estate this is a matter for the executors or, if there is no will, for administrators appointed by the court. Arrangements in Scotland: the Procurator Fiscal

4.1 The Procurator Fiscal system is unique to Scotland. However, the law surrounding retention of tissue at post-mortem

This Code of Practice applies to police officers only, but the Crown Prosecution Service suggests that this may well be a good reference point for others such as pathologists and other experts.

examinations in Scotland is similar, although the practices of individual Fiscals may vary.

4.2 The Procurators Fiscal's remit is somewhat wider than that of Coroners: their role in common law is to determine the cause of death in uncertified and suspicious deaths, to exclude foul play and criminality in relation to any death, to allay public anxieties about any deaths and to maintain accurate death statistics. They will specifically authorise the removal of organs and tissues at the time of the post-mortem examination for laboratory studies such as neuropathology, microbiology, toxicology, etc. as required to determine the primary and contributory causes of death. They will take full cognisance of objections to an autopsy by the bereaved relatives and indeed can totally dispense with an autopsy in determining the cause of death.

4.3 No inquests are held in Scotland and, solely in relation to deaths at work due to the occupation of the deceased or deaths in custody, a Fatal Accident Inquiry (FAI) is mandatory. In other instances, which are quite infrequent, the FAI is at the discretion of the Lord Advocate - the most senior legal official in Scotland.

4.4 Bodies are released as soon as possible after the death has occurred even in cases of homicide, and most frequently within a maximum of a two weeks from death.

4.5 In cases of interest to the Procurators Fiscal, they have the right to prohibit any organ or tissue retrieval for transplantation purposes.

4.6 The Procurators Fiscal cannot authorise the removal of organs and tissues for research or teaching purposes, and if such material is required, the additional separate agreement of relatives of the deceased must be sought specifically.

Post-mortem examinations performed with relatives' agreement

Agreement to post-mortem examinations

5.1 The HTA 1961 requires that the person in lawful possession of the body makes

reasonable enquiries to determine that the deceased had expressed no objection while alive to a post-mortem examination being carried out under the HTA 1961 and that no relatives object.

However, in practice, hospitals require a relative's written agreement to the examination given on a standard form.

5.2 Ethically, it is important that any tissue retained must match the relatives' perception of what they agreed to being retained and its purpose. The form of agreement for post-mortem examination and the accompanying information must be sufficiently explicit and unambiguous so that the relatives' understanding of what they are likely to be requested to agree for retention will match the pathologist's requirements where these are known in advance. The form of agreement must also distinguish between retention for the purposes of verifying the cause of death and investigating the effects of treatment and retention for medical education and research. Relatives must also be given options for the lawful disposal of any tissue or organs retained for verifying the cause of death and investigating the effects of treatment; these options should include allowing their further use for medical education and research.

5.3 The retention of tissue samples (here intended to be sufficient to provide for histological processing) and fluids for laboratory investigation for verifying the cause of death and investigating the effects of treatment is an integral component of the post-mortem examination; therefore, this must be included in the agreement for the post-mortem examination itself. The retention of whole organs for verification of the cause of death and investigation of the effects of treatment must also be explicit and subject to agreement.

5.4 A senior and properly trained doctor, preferably a consultant, who knew the relatives best during the patient's last illness should obtain agreement to the postmortem examination. This doctor is in the best position to explore with relatives the depth of explanation that they require and provide answers to their questions. Wherever possible the clinician, before requesting relatives' agreement, should liaise with the pathologist who will perform the post-mortem examination so that guidance can be given to

the relatives on which organs are likely to be retained and for what period and purpose. Relatives should be informed that a pathologist can be available to answer any specific questions and concerns. Junior doctors are often required to seek agreement, but they must receive appropriate training; indeed, training in these aspects of bereavement must form part of the undergraduate medical curriculum and general professional training. Trained bereavement counselling officers may also have medically-delegated responsibility for seeking agreement in some hospitals, but relatives must be given the opportunity to speak to a senior doctor who understands why the post-mortem examination is necessary and what will happen during and after it. Relatives must be allowed a reasonable period of time before deciding whether to agree to a post-mortem examination. Pathologists must be willing also to speak to relatives, on request, after the autopsy and this is best done in liaison with the patient's clinician.

Post-mortem examination of fetuses, infants and children

5.5 The HTA 1961 applies only to those who were born alive. However, for the examination of fetuses delivered dead, written parental agreement must be obtained regardless of gestational age. This simple courtesy is a humane and pastoral act by the doctor and it may assist the bereavement process. If the body ought to be moved to another hospital for the examination, the agreement of the parents should be sought after the reasons for this and the means of transport have been explained to them.

5.6 Asking parents to agree to the post-mortem examination of a baby or young child is a difficult and challenging task and must be the responsibility of a senior member of the clinical team. Specific guidance on approaching parents and obtaining their agreement has been produced by the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI, 1998). Retention of tissues, organs and body fluids for medical education, training and research

5.7 Agreement must be obtained if the primary purpose of retention is specifically for teaching (e.g. for display in a pathology

museum), for training (e.g. for use by surgical trainees), or for research. If a large specimen (e.g. whole organ or a slice of a whole organ) is to be retained for a museum then the long-term educational use must be explained before written agreement is obtained. (See also paragraph 1.8)

5.8 If the primary purpose of retention is for research, then agreement is required with approval of a Local or Multicentre Research Ethics Committee.

Individual grant-giving bodies may set more stringent standards for the use of tissue in research.

5.9 The guidance in '*Good Medical Practice*' (General Medical Council, 1998) is that all research protocols must be approved by a properly constituted research ethics committee. A Local or Multi-Centre Research Ethics Committee should be asked to comment on whether the residue of tissue samples originally taken for post-mortem diagnosis can be used for education or research once the diagnostic examination has been completed. Research on residual tissue (i.e. tissue that would normally be discarded or archived after diagnostic examination) may not require individual agreement provided that, first, excess tissue was not collected for this purpose at the time of the postmortem examination and, second, it is used by the investigator without patient identification details. The guidance in '*Human Tissue: Ethical and Legal Issues*' (Nuffield Council on Bioethics, 1995) applies mainly to tissue removed from living individuals.

5.10 The use of retained tissue for genetic tests presents particular problems extending beyond the scope of these guidelines. A Code of Practice is given in *Recommended policies for uses of human tissue in research, education and quality control* (1997). This issue is also dealt with in *The consensus statement of recommended policies for uses of human tissue in research, education and quality control* (RCPATH, 1999). Pathologists must satisfy themselves that issues such as relatives' agreement, ethical approval, confidentiality, and implications for surviving relatives have been adequately addressed before providing tissue for genetic testing. There may be cases in which the pathologist should give due consideration to the need for the retention

and storage of samples for future mutation detection, which may either be to confirm a diagnosis or to establish a family-specific mutation.

Retention for treatment

5.11 The retention of tissue for transplantation, as well as for medical research and education, is governed by the Human Tissue Act (1961). The donation of tissues and cells requires explicit agreement from relatives (see also paragraph 1.8), which must be recorded on a separate form. In some centres this is undertaken by the transplant co-ordinator.

5.12 The use of fetal tissues for research and treatment has been covered in a previous report (*Review of the guidance on the research use of fetuses and fetal material. 1989*) which sets out strict guidelines placing barriers between the decision to carry out an abortion, the procurement of tissue, and its subsequent use. Local Research Ethics Committees must approve the use of fetal tissues.

Retention of whole organs

5.13 Retention of whole organs after post-mortem examinations conducted with relatives' agreement (see also paragraph 1.8) may be necessary to enable further detailed analysis, often requiring prior tissue fixation. This may also enable an enhanced understanding of the cause of death through discussion with colleagues. With regard to post-mortem examinations on fetuses and small infants, the organs are often so small that their retention and histological processing is the only practical option.

5.14 Written agreement must be obtained for the retention of whole organs in all cases. Organs must not be retained without relatives' agreement. The prospect of distressing relatives is not a valid reason for not seeking their agreement. Experience shows that agreement is usually given if the reasons for retaining the organ are sound and carefully explained. Conversely, extreme distress can be caused by later discovery that organs have been retained without relatives' knowledge or agreement. (See also paragraph 1.8)

5.15 If the necessity for or desirability of retaining a whole organ has not been predicted before the examination, the organ should be retained pending immediate steps to obtain written agreement (for example, with the assistance of the deceased's general practitioner); if this is refused, the organ must be returned to the body.

5.16 If agreement for the retention of the whole organ has not been obtained or is refused then other approaches can be considered and, if necessary, discussed with the relatives:

- retention of only part of the organ, returning the other part to the body;
- where and if appropriate, rapid fixation (e.g. by microwave fixation) and examination with return of the organ to the body before it is released;
- recording (e.g. video) the examination (for example for congenitally malformed hearts).

Relatives must be advised clearly of the benefits of retaining a whole organ where this is considered to be essential in investigating the deceased's illness. In turn, it is reasonable for the relatives to expect that the results of that investigation, when completed, will be explained to them.⁸

5.17 Relatives giving their agreement to the retention of tissues or organs should be offered the option of allowing the hospital to respectfully dispose of the residual material at the conclusion of the further examination.⁹ Alternatively, arrangements can be made for collection of a temporarily retained organ, preferably by a funeral director chosen by the relatives, at some specified time after the post-mortem examination, so that they can arrange for disposal in accordance with their wishes.

Limited post-mortem examination

5.18 Limited post-mortem examination is no substitute for a full post-mortem examination, but may provide answers to specific questions. Clinicians and pathologists should be flexible in respecting the wishes of relatives, which must be clearly stated on the form of agreement and may allow options such as:

- examination limited to a single body cavity;

⁸ The rules of medical confidentiality apply even after death. Relatives are not necessarily entitled to know everything about the deceased and information should be released only on the judgement of the individual medical practitioner.

⁹ The procedure in HSG(91)19 (Disposal of fetal tissue) may be a model for "respectful disposal". Thus, having taken account of the wishes of relatives, the tissue should be disposed of by incineration. Prior to incineration the tissue should be stored in a secure container in a safe place. The container must be made of opaque materials and be used to transport the tissue to the incinerator.

- examination restricted to a single organ;
- examination performed through a pre-existing surgical incision;
- needle sampling;
- external examination supplemented where appropriate by radiology, photography, microbiology, and skin biopsy for chromosomal analysis (e.g. in perinatal pathology).

5.19 Limited post-mortem examination should not become a substitute for full post-mortem examination. The benefits of the full examination should be understood before relatives agree to a limited examination which may be inconclusive.

Disposal of tissue retained at any post-mortem examination

5.1 When a post-mortem examination has been completed and the report issued, a decision must be made about the fate of any retained tissue. In the case of hospital post-mortem examinations, relatives must be informed that processed (i.e. wax embedded) tissue may be archived safely and securely as tissue blocks, unless they wish to make their own arrangements for lawful disposal. When agreement was obtained for organ retention, then its ultimate fate must be discussed at that time; this could be to release it for lawful disposal,¹⁰ to retain it for medical education and research, or for the hospital to respectfully dispose of it (see footnote 9 for a description of what constitutes 'respectful disposal' in this context).

5.2 We recommend strongly that all histopathology and forensic pathology services have written standard operating procedures and protocols for the disposal of tissues including regular review of tissue stores and maintenance of accurate records of the disposal of all specimens. For post-mortem examinations required by law, these protocols should be discussed with and approved by the local Coroners or Procurators Fiscal.

5.3 Coroners have discretion with regard to the period for the retention of tissues. In many areas, Coroners authorise disposal once an inquest is closed. At that point, responsibility reverts in practice to the

pathologist; however, its further use or disposal is subject to relatives' wishes where these can be ascertained. A reasonable compromise is to archive the processed tissue blocks and histological sections, and to retain unprocessed tissue for the same period as biopsy and surgically-resected tissues unless relatives have expressed wishes to the contrary, or litigation is pending.

6.4 The person advising and seeking the agreement of relatives should notify them, preferably with a written copy of the information, that:

- where feasible, organs will be re-united with the body before release for burial or cremation;
- where organs cannot be re-united, the relatives can either make their own lawful arrangements or agree to respectful disposal by the hospital after the investigations (clinical or legal) have been completed;
- unprocessed tissue (i.e. surplus to that needed for histological processing) will be respectfully disposed of after the sampling has been completed unless the relatives wish to make their own lawful arrangements.

6.5 In cases where criminal charges have or may be made, then the Coroner may ascertain the advice of the local Chief Crown Prosecutor before disposal of any samples or tissues (see paragraph 3.7).

6.6 We recommend that, where the body of the deceased has already been buried or cremated, any remaining tissue which is not to be respectfully disposed of or, with agreement, to be retained for medical education or research, is wherever possible released only:

- with authoritative confirmation of the identity of the organs/tissue and of the deceased;
- to funeral directors chosen by and acting on behalf of those who have legitimate responsibility for the disposal of the body; and
- where the burial or cremation authorities have agreed in principle to accept the remains for disposal.

This does not preclude retained material being released directly to those who have

¹⁰ Although, under the HTA 1961, the spouse or, if none, a surviving relative may agree to post-mortem examination and retention of tissue, the person with legal authority to arrange the funeral and disposal of the body is the executor of the deceased's will (or, if intestate, the next of kin). In practice, the spouse or other family member usually makes the funeral arrangements.

legitimate responsibility for its disposal, but it would be sensible to ensure that the proposed method of disposal is lawful and safe. In that context, we recommend that the recipient and the burial or cremation authority must be notified of any hazards associated with the tissue and its fixative (e.g. formalin), and that confirmation must be obtained that they are able and willing to handle them in accordance with the appropriate COSHH regulations. The cremation of organs or tissues is enabled by The Cremation (Amendment) Regulations 2000 (in England and Wales).

Conclusions

7.1 While some of these guidelines are self evident, and others are already common practice, it is acknowledged that full implementation requires continuing liaison between the public, pathologists, legal authorities, and funeral directors. Because clinicians and (in post-mortem examinations directed by law) Coroners and Procurators Fiscal explain the need for post-mortem examination to relatives and, when required, seek their agreement, it will be necessary for the Royal Colleges, legal authorities and professional bodies to co-operate in implementing these guidelines. Medical staff requesting post-mortem examinations or dealing with relatives' enquiries must be apprised of the legal, ethical and emotional aspects, and also the medical indications for and importance of organ retention. These principles have important implications for undergraduate medical education and postgraduate training.

7.2 Advances in medicine and in pathological techniques, and changing public attitudes and legislation, render it impossible to anticipate every situation relating to tissue or organ retention. Implementing the recommendations in these guidelines will inevitably reveal aspects needing modification or further clarification.

Therefore, these guidelines should be reviewed periodically and, if necessary, amended.

Summary of recommendations

8.1 Medical schools and hospitals must provide training for medical, and other appropriate personnel (e.g. nurses, bereavement counselling officers), in requesting and obtaining agreement for post-mortem examinations and in dealing with relatives' concerns about tissue and organ retention. This must form part of the induction programme for house officers, senior house officers and specialist registrars in all disciplines. Similar information must be provided for nurses and other members of the health care team.

8.2 Doctors, or other appropriate suitably trained personnel, seeking agreement for a post-mortem examination must first liaise with the pathologist to determine the necessity of and grounds for retaining tissue so that relatives can make informed decisions.

8.3 Hospital authorities must provide an information leaflet for relatives explaining the purpose of postmortem examinations, the medical benefits of tissue and organ retention, and their rights to grant or withhold their agreement. The Royal College of Pathologists' model information leaflet is available (Annex A).

8.4 Relatives agreeing to post-mortem examinations must be given and keep a copy of the form they signed and a copy of the information provided to them. This information must relate to the post-mortem examination itself and any retention of tissues and organs.

8.5 Hospital authorities must ensure that postmortem examination forms offer relatives a range of options for which they can separately grant or withhold their agreement. A model form is included in this document as Annex B.

8.6 Relatives of those undergoing post-mortem examinations directed by law (Coroners and Procurators Fiscal) should be provided with an information leaflet explaining the legal necessity, in certain circumstances, to retain tissues or organs and of their rights to the material when the examination has been completed (see Annex

C). This leaflet should also explain the value of donation of tissues, such as aortic valves, for the treatment of living patients, and outline the mechanisms by which agreement to this can be given.

3.7 Reports of post-mortem examinations required by law should state clearly what, if any, tissues or organs have been retained in pursuance of the investigation of the death.

3.8 Hospital and forensic histopathology services must have standard operating procedures for the archiving and disposal of tissues retained from postmortem examinations, ensuring that their disposal procedures meet with public expectations. The storage of retained material must be safe and secure, and the method of disposal must be respectful, safe and lawful.

3.9 In cases where the body of the deceased has already been buried or cremated, any remaining tissue which is not to be respectfully disposed of or, with agreement, to be retained for medical education or research, should wherever possible be released only with authoritative confirmation of the identity of the organs/tissue and of the deceased, to funeral directors chosen by and acting on behalf of those who have legitimate responsibility for the disposal of the body, and where the burial or cremation authorities have agreed in principle to accept the remains for disposal. This does not preclude retained material being released directly to those who have legitimate responsibility for its disposal, but the proposed method of disposal must be lawful and safe. The recipient or the burial or cremation authority must be notified of any hazards associated with the tissue and its fixative (e.g. formalin), and confirmation must be obtained that they are able and willing to handle them in accordance with the appropriate COSHH regulations.

3.10 These guidelines should be reviewed periodically and, if necessary, amended in the light of advances in medicine and in pathological techniques, and changing public attitudes and legislation.

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The Royal College of Pathologists

Examination of the body after death

Information about post-mortem examination for relatives

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Glossary of terms

This information (Annex A) is available as a separate leaflet from the Royal College of Pathologists.

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Summary

Post-mortem examinations (PMs) provide valuable information on the cause of death and can provide vital information for future treatment and research.

There are two types of post-mortem:

1. Post-mortem examinations required by Coroners (or by the Procurator Fiscal in Scotland). These are investigations required by law and do not require the agreement of relatives.
2. Consented post-mortems, which are requested by doctors or by relatives. Full signed agreement must be given by the relatives for this type of postmortem to be carried out. Relatives can make restrictions for this type of post-mortem. Relatives should be fully informed before giving their agreement.

Introduction

Thank you for considering giving your permission for a post-mortem examination (also called an autopsy or a necropsy) to be held on the body of your relative. We appreciate that this will be a difficult decision for you. This guide aims to give you practical information about the post-mortem examination. A post-mortem examination may help doctors improve their treatment of future patients.

Also, as relatives you have a right to know anything about the illness of your relative that may affect your own health. Some illnesses are hereditary and the post-mortem examination may provide you with this information.

There is a glossary of words used at the back of this booklet to assist you, but please ask the person who gave you this if there is something you are unclear about or would like explained in more detail. It is important that you feel that you have enough information before making a decision about whether to agree to a post-mortem examination or to the keeping of tissues or organs.

The post-mortem examination

What is a post-mortem examination?

A post-mortem examination is the final step in the investigation of your relative's illness. It is a careful internal examination of the person who has just died and can give valuable information about an illness and its effects on the body. It may tell us more precisely why your relative died.

However, even the most detailed post mortem investigation will often leave some questions unanswered. Post-mortem examinations are carried out by a pathologist, who is a doctor specialising in the laboratory study of disease and of diseased tissue, assisted by a technician who is a person with specialist training to assist pathologists. They are carried out in special facilities provided in the hospital mortuary. In certain circumstances they may be carried out in the local public mortuary, or in a regional centre for specialist post-mortem. The body will be moved respectfully from the place of death to where the examination is to be carried out.

Pathologists perform post-mortem examinations to standards set by the Royal College of Pathologists. These standards include carrying out the examinations in a respectful manner and with regard for the feelings of bereaved relatives.

First, the pathologist carries out a careful external examination of the body. Photographs and X-rays are sometimes taken for more detailed study. The internal part of the post-mortem examination then begins. An incision is made down the front of the body and internal organs are taken out for a detailed examination. Sometimes the examination can be performed through a pre existing surgical incision. When the brain is to be examined an incision is made in the hair at the base of the head. Small tissue samples are usually kept for further investigations with a microscope. When detailed laboratory investigations require particular body parts or organs to be kept for some time, you will be asked to give your written agreement. The form you sign must indicate whether you agree to any organs being kept and, if so, for what purpose and how you wish them to be dealt with when their examination is complete.

The benefits of a post-mortem examination

A post-mortem examination can give valuable information about an illness and its effects on the body and may explain why your relative died. This information may make it easier for you and other family members to come to terms with the death. Post-mortem examinations can also provide valuable information which can help doctors to treat other patients with the same kind of illness and can provide vital information for research.

Types of post-mortem examination

There are two types of post-mortem examination.

1. The first is the Coroner's post-mortem which applies in England, Wales and Northern Ireland. The equivalent of the coroner in Scotland is the Procurator Fiscal. When a post-mortem examination is requested either by the Procurator Fiscal or by the Coroner, the agreement of relatives is not required. In the United Kingdom, most post-mortem examinations are required by the Coroner or Procurator Fiscal. They are performed to investigate:
 - sudden and unexpected deaths
 - deaths where the cause is unknown and the doctor cannot issue a death certificate
 - death where the cause of death is known to be, or suspected to be, due to causes other than natural disease (for example, accidents and industrial diseases).
2. The second type of post-mortem examination is the Consented post-mortem which is done usually at the request of the doctors who have been caring for your relative or sometimes at the request of close relatives wishing to find out more about how a person in their family died. This type of post-mortem can be done only with your written agreement.

Coroner's post-mortem examination (Procurator Fiscal in Scotland)

The Coroner is an independent officer with statutory responsibility for the legal investigation of some categories of deaths. The doctors who have been looking after your relative must discuss the case with the Coroner if the death has occurred under some circumstances (for example, if death is known or suspected to be due to an accident or to industrial disease). If the Coroner decides that a postmortem is required, the pathologist will be asked to carry this out and report the findings to the Coroner. In these circumstances the pathologist acts for the Coroner and is independent of a hospital. Your agreement is not required.

The Coroner will subsequently issue the Medical Certificate of Death and his officer will get in touch with you to let you know when to proceed with the funeral arrangements. If an inquest is required, it will be opened and then adjourned to allow the funeral to take place. The inquest (or in Scotland a fatal accident inquiry) will be held several weeks later when all the results from the post-mortem examination are available.

Consented post-mortem examination

If a Coroner's post-mortem examination is not required the doctors may ask you to agree to a post-mortem examination of your relative. This may help the doctors give you, if you wish, more detailed information about why your relative died, and may also contribute to the development of new ways of treating future patients with similar problems. If you agree to a Consented post-mortem examination the doctors will issue the medical certificate of death before the post-mortem so that you can proceed with the arrangements for the funeral.

Consented post-mortem examinations can be:

- **Full**
This involves a detailed examination of all the internal organs including the brain, heart, lungs, liver, kidneys, intestines, blood vessels and small glands, which are removed from the body, examined in detail and then returned to the body.

Limited

You may be uncomfortable with the idea of a full postmortem examination. If that is the case you may be asked to consider agreeing to a limited post-mortem examination. This could involve examination only of those organs directly involved in your relative's illness. For example, if someone has died of a stroke then only the brain and blood vessels supplying the brain might be examined. It is important to remember that the pathologist will only examine organs and/or small pieces of tissue which have already been agreed between you and the doctor who was looking after your relative. This may, however, mean that no information will be available about possible abnormalities present in other organs, but which may have contributed to the death of your relative.

Some of your questions answered...

When will the post-mortem be carried out?

The initial post-mortem examination is carried out as soon as possible after death, usually within two to three working days. You will be given time to discuss the request to carry out a post-mortem examination. When religious observance requires a funeral within 24 hours, every effort is made to carry out the post-mortem within that period. The actual examination can take up to three hours. However some post-mortem examinations may take longer, particularly if tissues or organs are kept for detailed examination; this could only delay the funeral if you wanted the tissues or organs to be reunited with the body before burial or cremation. Laboratory investigations which are carried out after the post-mortem examination may take several weeks.

Will a post-mortem delay the funeral?

As the post-mortem is normally carried out within two to three working days after death, funeral arrangements should not need to be delayed. Your relative's body is usually released to the undertaker on the day of the postmortem.

When the post-mortem has been carried out

late in the afternoon, this will happen usually in the following morning. However, sometimes the investigations are very complex, requiring a very detailed examination of the organs. This may take several days or even weeks, thus risking a delay to the funeral but only if you wish to have any retained tissue, organs or body parts reunited with the body.

Will the body be disfigured?

After the post-mortem the technician will prepare your relative's body for you to see again, should you wish. The internal examination involves an incision down the front of the body, which cannot be seen when your relative is dressed. There will also be an incision concealed in the hair at the back of the head if the brain has been examined.

Do relatives have to give their agreement to the post-mortem examination?

Unless the post-mortem is directed by law at the request of the Coroner or Procurator Fiscal, your agreement must be obtained before any investigations are carried out. Relatives do not have to give their agreement unless they wish to. You should give your agreement only after you have had the purpose of the post-mortem examination explained to you and you have had sufficient opportunity to ask questions before reaching a decision. You may need time to consider whether to give your agreement and to talk to other family members. You should not give your agreement if you know that another close relative would object, or has already objected to the post-mortem examination.

Why do we ask if we can keep some organs?

When a post-mortem examination is first discussed with you, you may be asked whether the pathologist can keep a specific organ such as the heart, to enable medical staff to carry out a more detailed examination. The pathologist on behalf of the hospital would become custodian of the organ which would be kept in safe and secure conditions in the hospital. The identity of the organ and the diagnosis would be confidential, treated in the same confidential

manner as all medical records.

Often the doctors would like to keep the organ indefinitely. This is because the long term availability of the organ provides an opportunity to learn important information about the underlying condition and its treatment both now and in the future. If you agree to an organ being kept indefinitely, you will be asked to confirm your agreement in writing. If in the future you should change your mind we can, in consultation with you, respectfully dispose of the organ or return it to you for cremation or burial as you may wish. The reasons why the pathologists may wish to keep an organ, tissue or body parts must be explained to you. These reasons may include:

- to determine the cause of death
- specific current research projects
- archiving for future research projects
- medical museums for the education and training of medical students and doctors
- discussions between other clinicians and pathologists.

You may:

- wish to ask about the implications for agreeing to these uses
- like to ask whether tissue, parts or organs will be sent to medical museums, or used for genetic research or commercially
- wish to know whether parts will be sent to another laboratory, to tissue or organ banks or abroad
- wish to know whether you are likely to be involved in any extra expenses.

If you do not wish us to keep an organ indefinitely, you will be asked whether you would allow us to keep it for several weeks so that the pathologist and other doctors can examine it in detail before issuing the post-mortem report. We can then respectfully dispose of the organ or return it to you for cremation or burial as you wish.

It is important that, if you do not wish us to retain an organ or any organs at all, you inform us when permission to carry out a post-mortem examination is discussed with you. It is important that you record on a specially prepared consent form what you agree to. You will be given copies of any consent forms to keep.

You may prefer to agree to the pathologist

carrying out the post-mortem and keeping what is considered necessary without going into specific details.

Will the relatives be able to find out the results of the post-mortem examination?

A report on the post-mortem examination will automatically be sent to the consultant who looked after your relative or to the Coroner in the case of a post-mortem requested by the Coroner. A report may also be sent to your relative's general practitioner. As these reports are usually written in medical terminology it may be helpful to have the results explained to you. You can ask for an appointment with the consultant who had looked after your relative, or with your relative's GP or with the pathologist who carried out the post-mortem examination. They can then discuss the results with you. If you wish, the pathologist can also produce a report in non-medical language which will be sent directly to you.

March 2000

Glossary of terms

Archiving

Archiving is the long-term preservation of tissue or organs. Archives are important and useful because:

- the preserved tissue or organ can be re-examined if new diagnostic techniques or fresh knowledge about diseases might give a clearer explanation of the **deceased's illness**
- the education and training of medical students and doctors is helped if they can see for themselves what happens inside the body in disease
- research using archived tissues and organs can help in the diagnosis and treatment of future patients.

Tissue and organ banks

Rare diseases can be investigated properly only when a sufficient number of cases have been studied. This often means that, subject to agreement in individual cases, tissue or organs from post-mortem examinations may be stored safely and securely in a tissue or organ bank until enough cases have been collected and then the research can begin.

Body parts

Body parts are groups of organs or a limb or part of a limb.

Consented post-mortem examination

Post-mortem examinations performed with the agreement of relatives are called consented post-mortem examinations.

Coroner

The Coroner is required by law to investigate deaths due to unnatural, suspicious or unknown causes. In some cases, the Coroner may hold an inquest. The Coroner is assisted by Coroner's Officers. Coroner's post-mortem examination Most post-mortem examinations in the UK are performed at the request of Coroners. The agreement of relatives is not required. Attendance at an inquest is necessary in only a minority of cases.

Fatal Accident Inquiry

Fatal Accident Inquiries are held only in Scotland by the Procurators Fiscal (the equivalent of Coroners). They are similar to inquests.

Fixing

Before organs or tissues can be examined in detail, particularly with a microscope, they have to be hardened by immersion in a chemical, usually formaldehyde. This is known as fixing. The complete process may take several weeks.

Full post-mortem examination

The full post-mortem examination involves examination of the brain and other parts of the skull and of all the contents of the chest and abdomen.

Inquest

Inquests are held by Coroners when death is known or suspected to be due to anything other than natural causes. Sometimes they are held in the presence of a jury. The purpose is to consider all the evidence relevant to the death and to give relatives, or their legal representative, an opportunity to question witnesses.

Incision

An incision is a cut in the skin, enabling the body to be opened. The incision is made in the same way as for a surgical operation. The incision is closed at the end of the post-mortem examination.

Limited post-mortem examination

A post-mortem can be limited, in consented post-mortem examinations and if relatives so wish, to one body cavity (for example, the chest). This may not provide all possible information about the cause of death.

Medical Certificate of Death (Death Certificate)

The death certificate is a document required by law. It enables the Registrar of Deaths to issue a form permitting disposal of the body. It also gives the cause of death; this is important for recording the incidence of diseases in the UK, but research has shown that up to 30% of the information on a death certificate may be wrong unless it is based on findings from a post-mortem examination. The cause of death written on the certificate can be changed later when the results of a post-mortem examination are available. Mortuary The mortuary is a group of rooms, usually in a hospital (those outside hospitals are called public mortuaries), where bodies are kept in refrigerators before collection by undertakers. The mortuary also includes the post-mortem room where the post-mortem examination is performed.

Organ(s)

The body contains many organs such as the brain, heart, kidneys, lungs and liver. Each organ carries out different functions. The organs are connected in the body by nerves, blood vessels and fibres.

Regional Centre for specialist post-mortem examination

Sometimes it is necessary for a body to be moved to another place for the post-mortem examination where there are special facilities and pathologists skilled in dealing with particular cases (for example, deaths in infancy and childhood).

Pathologist

A pathologist is a medical doctor trained in the diagnosis and study of disease. Pathologists who perform postmortem examinations usually work in hospitals and are involved in the diagnosis of disease in patients; these pathologists are called histopathologists. Pathologists work to standards laid down by the Royal College of Pathologists.

Procurator fiscal

The Procurator Fiscal is the Scottish equivalent of a Coroner.

Tissue

Organs contain tissue, collections of cells which give organs their special functions. For example, the heart contains muscle tissue composed of cells which contract to pump the blood. Samples of tissue (typically small slices about 1/4 inch thick) are usually taken during a post-mortem examination for examination with a microscope; this involves treating the tissue with chemicals and embedding it in wax; this wax-embedded tissue is then kept safely and securely so that it can be re-examined later if necessary.

Technician

A technician is a person, often a scientist, with special training to assist pathologists in the diagnosis of disease. Some technicians help the pathologist carry out the postmortem examination; others prepare any tissue that has been kept for study with a microscope.

Agreement to a post-mortem examination

I, _____ do not object to a post-mortem examination being carried out on the body of _____ in order to find the cause of death and study the effects of treatment. I understand that this examination may involve **tissue samples or fluids being taken and held for laboratory investigation.**

If the deceased is an adult has he or she ever expressed an objection to this type of examination (as far as you know)?
 Yes No

Limited post-mortem examination

You may limit the extent of the examination. The person who gave you this form will explain the options and implications to you.

Do you wish to limit the examination? Yes No

If 'Yes', where do you want the examination limited to?

- The head
- The chest
- The abdomen

Organs being taken and held

You may agree or disagree to whole organs being taken for any further examination which could provide a more detailed understanding of the illness.

Tick one of the statements below to indicate whether or not you agree to organs being taken and held

- I do not object to any organs being taken for further investigation if this is necessary to fully understand the cause of death and effects of treatment/
- I object to any organs being taken for further investigation.
- I object to the following organs being taken for further investigation. (Please list organs below)

Disposal of any tissue or organs taken

After any further investigations of tissue or organs taken, those tissue samples or organs must be disposed of in a lawful way. You can either arrange this yourself or the hospital can do it. Tick one of the statements below to show how any tissue samples or organs should be disposed of.

- The hospital may dispose of the tissue samples or organs in a lawful and respectful way
- I will arrange for the tissue samples or organs to be disposed of in a lawful way.
- I prefer the tissue samples or organs to be reunited with the body before it is released, even though this may delay the funeral.

Medical research and education

You may agree or disagree to some tissue, fluids or organs being taken and held for an unlimited time for medical research and education.

Tick one of the statements below to show whether or not you agree to any tissue, fluids or organs being taken and held for an unlimited time for medical research and education.

- I do not object to any tissue, fluids or organs being taken for medical research and education.
- I object to any tissue, fluids or organs being taken for medical research and education
- I object to the following tissue, fluids or organs being taken for medical research and education. (Please list the tissue, fluids and organs below)

Please read the 'Information for Relatives' attached before you sign this form.

Your signature: _____ Relationship to deceased: _____ Date: _____	Witness's signature: _____ Name: _____ Position: _____
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For post-mortem examinations required by law

Name of deceased

Disposal of any tissue or organs taken

After any further investigations of tissue or organs taken, those tissue samples or organs must be disposed of in a lawful way. You can either arrange this yourself or the hospital can do it.

Tick one of the statements below to show how any tissue samples or organs should be disposed of.

- The hospital may dispose of the tissue samples or organs in a lawful and respectful way
- I prefer the tissue samples or organs to be reunited with the body before burial or cremation, even though this may delay the funeral.
- I will arrange for the tissue samples or organs to be disposed of in a lawful way.

Medical research and education

You may agree or disagree to some tissue, fluids or organs being taken and held for an unlimited time for medical research and education.

Tick one of the statements below to show whether or not you agree to any tissue, fluids or organs being taken and held for an unlimited time for medical research and education.

- I do not object to any tissue, fluid or organs being taken for medical research and education.
- I object to any tissue, fluid or organs being taken for medical research and education
- I object to the following tissue, fluids or organs being taken for medical research and education. Please list the tissue, fluids and organs below)

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Please read the 'Information for Relatives' attached before you sign this form.

<p>Your signature:</p> <p>-----</p> <p>Relationship to deceased:</p> <p>-----</p> <p>Date:</p> <p>-----</p>	<p>Witness's signature:</p> <p>-----</p> <p>Name:</p> <p>-----</p> <p>Position</p> <p>-----</p>
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