



HUMAN TISSUE ACT 2004

BRIEFING FOR FORENSIC PATHOLOGISTS

INTRODUCTION

1. The Human Tissue Act applies to England, Wales and Northern Ireland except for provisions introducing a new offence of having material with a view to testing the DNA within it without consent, which also applies in Scotland.
2. Following public concern over the retention of human tissue, in particular from the deceased, the Government reviewed the current law relating to the keeping and use of tissue from both the living and those who have died. It became clear that the law had gaps, was unclear and inconsistent. The Human Tissue Act 2004 is intended to set out a new consistent legal framework for issues relating to the taking, retention or use of human tissue and organs from adults or children, for health-related purposes and for public display.
3. The Act repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984, and the Human Organ Transplants Act 1989 as they relate to England and Wales, and the corresponding legislation in Northern Ireland.
4. The introduction of such a framework clearly impacts on the work of forensic pathologists and this briefing has therefore been issued.
5. The purpose of the briefing is to outline the main legislative changes. It is not to provide detailed guidance on the application of the Act. Such guidance may be drafted once the Act has been implemented, see below, and the bodies created by the Act have come into existence and begun operation.

RESERVATION

6. The information provided in this briefing is based on the Home Office assessment of how the Act will operate. It must be stressed that the application of the Act will be determined by decisions made by the Human Tissue Authority and interpretation in the courts: this may be not be in line with the position stated herein.
7. This is not intended to be an exhaustive description of the Act but a summary of those parts that appear most relevant to forensic pathology.
8. Throughout this document it has been assumed that the determination of the identity of the deceased and the cause of death are the subject of an investigation by the coroner. It is further assumed that the police are investigating crime – but that this investigation does not include determining the cause of death. If these assumptions are not correct the position set out below will be incorrect.

STRUCTURE

9. The Act was drafted by the Department of Health to deal with issues within the context of its responsibilities. As a consequence the approach adopted may appear unusual to those more familiar with the criminal law. The main difference being that the central provisions of the Act only apply to acts done for a purpose specified in Schedule 1 of the Act. These are:
 - Anatomical examination;
 - Determining the cause of death;
 - Establishing after a person's death the efficacy of any drug or other treatment administered to him;
 - Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
 - Public display;
 - Research in connection with disorders, or the functioning, of the human body;
 - Transplantation;
 - Clinical Audit;
 - Education or training relating to human health;
 - Performance assessment;
 - Public health monitoring; or
 - Quality assurance.

10. The role of the forensic pathologist involves determination of the cause of death, including consideration of possible pre-existing disease and the wider circumstances of the death. Parts of this function, particularly determining the cause of death, falls within the scheduled purposes. However, the activities of others, with whom the pathologist may work (such as police or forensic scientists), who are not attempting to determine the cause of death does not.

11. The Act introduces a framework of controls based on the following:
 - Consent;
 - Regulation; and
 - Licensing.

CONSENT

12. Part 1 of the Act sets out a requirement that certain activities must only be undertaken with appropriate consent. Appropriate consent relates mainly to the person from whom consent should be sought. The activities include, when done for a purpose set out in Schedule 1, the following:
 - Storage of the body of a deceased person;
 - Use of the body of a deceased person;
 - Removal from the body of a deceased person of any relevant material;
 - Storage of any relevant material taken from a human body; or
 - The use of any relevant material which has come from a human body.

13. Relevant material is defined (section 53) as material, other than gametes, which consists of or includes human cells.

14. Section 11 of the Act exempts anything “done for the purposes of functions of a coroner or under the authority of a coroner” from the requirement for consent. It is believed that any activities authorised by a coroner under the Coroners Act 1988, or any common law power, would fall within the exemption.

Post-Mortem Examination

15. The performance of a post-mortem examination falls within the remit of the Act. Such examination would, apart for the section 11 exemption, require appropriate consent.
16. The effect of section 11 is to remove the consent requirement. Therefore a forensic pathologist undertaking a post-mortem examination under the provisions of the Coroners Act, or other power of a Coroner, will be exempt from the requirement for consent.
17. In this regard the advice from the Coroners Unit of the Department of Constitutional Affairs is that a second post-mortem authorised by the coroner falls within the section 11 exemption.

Taking Samples

18. During the post-mortem examination the forensic pathologist may take samples of “relevant material” from the body of the deceased for further analysis or perhaps to provide to others (e.g. toxicologists, neuropathologists etc.) for analysis. These samples may either be used to determine the cause of death or for the purposes of a criminal investigation.
19. Where the samples are to be used to determine the cause of death they fall within the controls set out in the Act. However, it is submitted that the analysis of such samples falls within the definition of “done for the purpose of functions of a coroner” and thus exempt from the provisions relating to consent.
20. Where the samples are taken to assist the investigation of a suspected crime they are not being used for a purpose set out in Schedule 1 of the Act and the requirement for consent will not apply.
21. The Coroners Rules 1984 (rules 9 and 12) require that the pathologist notify the Coroner of the samples retained.

Storage of Samples

22. Where samples are taken for the purpose of determining the cause of death under the authority of the coroner, the storage of those samples will be exempt from the consent requirement by virtue of section 11. This exemption subsists until the coroner’s requirement for those samples ends. The Coroners Rules (rules 9 and 12) require the Coroner to notify the pathologist of the period for which retained material may be held under his authority. At this point, subject to the following points, the continued storage will require consent.
23. Where samples are originally taken for the purpose of determining the cause of death (a scheduled purpose) and are no longer required for that purpose but are still required for the purposes of the investigation of crime or the criminal justice system then the

storage alters from being within the scope of the Act to being outside its provisions. Consent is therefore not required to retain materials for criminal justice purposes.

24. Where samples have been stored without consent by virtue of the section 11 exemption, or the requirements of the criminal justice system, and they are no longer required by the coroner or the criminal justice system then further storage will require consent where the storage is for one or more of the purposes in Schedule 1.
25. The Act does not impose requirements with regard to transportation of samples.

Use of Samples

26. The Act's provisions with regard to the use of samples are effectively the same as for storage. Consent is not required for work undertaken on behalf of the coroner (by virtue of section 11) or work for the purposes of the criminal justice system which is outside the remit of the Act (that is not for a scheduled purpose).
27. Once there is no requirement from either the coroner or the criminal justice system for the use of the samples such use will require consent where the use is for one or more of the purposes in Schedule 1.

Advice

28. The Act (section 5) creates a criminal offence in relation to carrying out an activity requiring consent without such consent. It also creates an offence of falsely representing that such consent has been granted or that the requirement does not apply. In both cases it is a defence to show that you reasonably believed (a) that such consent had been given or that (b) the requirement for consent did not apply.
29. Pathologists are advised, when the relevant parts of the Act have been implemented, to take reasonable steps to ensure their work has been authorised by the coroner (as is set out in the Code of Practice) before undertaking an activity which could require consent or advising others (e.g. mortuary staff) that such consent has been given or that it is not required.
30. The clearest means of ensuring the Coroner has provided authority is to have confirmation from the Coroner. However, this is not always a practical approach. In this regard it is advised that it would be reasonable to accept an assurance by a Coroner's Officer or police officer involved in the investigation. It would be sensible to record this information.
31. The discussion above notes that retention of material after the requirements of the coroner and the criminal justice system have lapsed requires consent if the retention is for a scheduled purpose. The Home Office advice is that material should not be retained without consent, even if the retention is for a non-scheduled purpose, unless on the authority of the coroner or under police powers.
32. Where material is no longer to be retained under the authority of the Coroner or police it should be retained or disposed of in an appropriate manner as discussed below.

Others

33. The police have powers, both under the common law and s19 Police and Criminal Evidence Act 1984, to seize evidence. It is important to note the Act does not interfere with these powers (there may be a restriction if material is to be taken for a scheduled purpose) and, as they are used for the investigation of crime (not a scheduled purpose), the controls will not apply. It is therefore open for the police to seize material (even relevant material) as evidence at the post-mortem examination.
34. Section 39 of the Act excludes activities taken in relation to criminal justice purposes from the regulatory framework and licence requirements of the Act (discussed below) but does specify that a post-mortem examination undertaken for a coroner is still covered. It is submitted that this requirement does not affect the position of police officers, or others, that may be present at such a post-mortem examination but not acting on behalf of the coroner. They are not undertaking the post-mortem examination and thus are not brought within the proposed controls.
35. Where samples of relevant material are requested by police, or others, in relation to the investigation of a crime a pathologist can assist by taking such samples. These are not taken for a scheduled purpose and the Act does not apply.
36. As discussed above both the coroner and the police have the authority to take samples from the body of the deceased. The Coroners Unit (then part of the Home Office, now part of the Department for Constitutional Affairs) issued advice in 2001, in relation to the use of those powers, which is still applicable and is worth restating.
 - Pathologists are urged to take only those samples they consider important in order to carry out a thorough investigation into all aspects of the death.
 - Where the police wish to take samples in addition to those taken by the pathologist (as part of the coroner's post-mortem examination) they should consult the coroner beforehand.
 - The Home Office is concerned that nothing, which might result in clear and obvious disfigurement of the body, should take place unless there is very good reason. Ideally the consent of the relatives should be obtained for such action but it is recognised that this may not be practical. However, it is suggested that any such action be explained to the relatives.

Other Consent Requirement - DNA

37. The Act (section 45) introduces an offence of possessing bodily material with intent to obtain a DNA profile from it, other than for an approved purpose, without appropriate consent. Schedule 4 (paragraph 5) of the Act includes exemptions from this provision for activities done for the purpose of a coroner, for the prevention or detection of crime and for the conduct of a prosecution.
38. It is submitted that the work of forensic pathologists in determining the cause of death or the investigation of crime will be outside the scope of this provision.

REGULATION

39. The Act requires the creation of the Human Tissue Authority (HTA) and sets up, under the HTA, the Inspectorate of Anatomy & Pathology (IAP) and the Inspectorate for Organs and Tissues for Human Use, to supervise different aspects of the use of human tissue. The IAP is the relevant Inspectorate in this context.

Human Tissue Authority

40. The HTA remit covers storage of bodies of deceased persons, storage of relevant material, post-mortem examinations, disposal of bodies of deceased persons and of relevant material. It will therefore have a role in forensic pathology. The Act proposes its general functions to include:
- Maintaining a statement of general principles which it believes should be followed;
 - Providing oversight and guidance;
 - Ensuring compliance with Part 1 of the Act (consent requirements) and such codes of practice as are issued under the Act; and
 - Issuing codes of practice to give practical guidance on activities within its remit or setting standards for such activities.
41. As stated above, the Act [section 39(1)] excludes acts undertaken for criminal justice purposes from the remit of the HTA but does state [section 39(2)] that post-mortem examinations undertaken under the authority of a coroner are within its remit. It is also notable that section 39(1) excludes acts undertaken for the criminal justice system from section 14(1) of the Act – which sets out the general remit of the HTA. It does not cover section 14(2) which specifies the HTA specific authority with regard to post-mortem examinations.
42. The result is that the post-mortem examination is subject to the supervision of the HTA regardless of the purpose of the examination (i.e. whether for a scheduled purpose or not) or the authority under which it is undertaken. Acts undertaken for criminal justice purposes, other than a post-mortem examination, are exempt from the supervision of the HTA.
43. This approach has been adopted by the Department of Health because there is a policy objective of regulating all post-mortem examinations, whether these are done on the authority of a Coroner or not, and whether or not there is also a criminal justice aspect to the post-mortem examination. Further, the requirement that such examinations comply with standards set by the HTA is unlikely to undermine, or interfere with, the criminal justice system.
44. Therefore work undertaken by forensic pathologists shall be subject to the supervision of the HTA and compliance with its codes of practice.
45. The Home Office in consultation with the Royal College of Pathologists have produced a code of practice in relation to forensic pathology. This sets out standards and provides guidance. The HTA draft Code of Practice sets out quality standards by reference to documents issued by the Royal College. The Home Office are working with the HTA with regard to the development of the codes.
46. Beyond the post-mortem examination it will also be necessary to work with the HTA on other areas where they are required to issue codes to ensure that any documents issued properly reflect the requirements of forensic pathology. Areas where the HTA may issue codes of practice include:
- The definition of death for the purposes of the legislation;

- Communications with the family of the deceased in relation to the making of a post-mortem examination;
 - The making of post-mortem examinations;
 - Communication with the family of the deceased in relation to removal of relevant material from the body of the deceased for use for a scheduled purpose;
 - The removal of relevant material from a human body for use for a scheduled purpose;
 - The storage for use for a scheduled purpose of the body of a deceased person and/or relevant material;
 - The import of a body or relevant material for use for a scheduled purpose; and
 - The disposal of relevant material.
47. The remit of the HTA, covering the removal from the body, storage and disposal of relevant material will also cover persons other than pathologists who have such material for scheduled purposes (not covered by the exemption in relation to criminal justice purposes). In particular the HTA remit will cover those undertaking storage and analysis of relevant material for the determination of cause of death (e.g. toxicologists).
48. It is important to note that the HTA supervision and code of practice in relation to the disposal of relevant material will apply to relevant material removed as part of a post-mortem examination irrespective of whether it was taken for a scheduled purpose [section 14(1)(g)(ii)]. However, the section 39 exemption applies so that relevant material taken for criminal justice purposes is not covered. The Home Office intends to work with the HTA to agree an appropriate approach to the disposal of relevant material.
49. It is important to stress that samples taken from the deceased must be treated with appropriate respect and, if appropriate, disposed of in a sensitive manner. The Coroners Rules 1984 (rules 9 and 12) require the Coroner to seek views on the appropriate manner for dealing with material when retention under the Coroner's authority ends. These include (a) burial, cremation or disposal by the pathologist; (b) return to an appropriate person or (c) retention for medical research or other purpose.
50. Although not mentioned in the relevant section the principle should be adhered to when material has been held, after the Coroner's authority has ended, for the purposes of the police or criminal justice system.
51. Where the pathologist has been informed of wishes expressed to the Coroner regarding the handling of material after retention he should, as far as practical, deal with it in accordance with those wishes. Where no wishes are expressed he should dispose of it in a respectful manner.
52. The Coroners Rules 1984 (rules 9A and 12A) require a record be kept of what has been done with the material.
53. Failure to comply with a code issued by the HTA will not, by itself, create criminal liability. However the Act (section 28) indicates such action may be taken into account by the HTA when making decisions on licensing.

Inspectorate of Anatomy and Pathology

54. The Act states that the IAP shall act on behalf of the HTA and carry out such functions of the HTA as are allocated to it.
55. It appears likely that the IAP shall act on behalf of the HTA in inspection and enforcement roles.

LICENSING

56. The Act (section 16) requires that certain activities may only be undertaken under the authority of an HTA licence. These include:
 - A post-mortem examination;
 - Removal of relevant material from a deceased person for a scheduled purpose;
 - Storage of the body of a deceased person for a scheduled purpose; or
 - Storage of relevant material for a scheduled purpose.
57. It is notable that the requirement for the activity to be for a scheduled purpose does not apply to a post-mortem examination. This must take place on licensed premises regardless of the purpose for which it is undertaken.
58. In light of the possibly broad interpretation of post-mortem examination the Act [section 39(3)] excludes any examination at the place where a body is found from the requirement for a licence. This ensures that the pathologist can examine the body at the scene without infringing the licence requirement.
59. It is clear from Schedule 3 of the Act that the licences granted by the HTA shall have certain characteristics. These include:
 - It shall specify the premises to which it applies;
 - It shall apply only to one location;
 - It shall designate an individual as the person under whose supervision the licensed activities will take place; and
 - It shall authorise only one activity.
60. It is the duty of the person designated in the licence to ensure all licensed activities are undertaken by suitable persons, that they adopt suitable practices and that any conditions in the licence are complied with.
61. The nature of the licences suggests they will be sought by, and granted to, persons in charge of premises e.g. mortuaries. It is anticipated that only where the forensic pathologist is in charge of the mortuary would it be appropriate for them to seek such a licence in relation to carrying out post-mortem examinations.
62. Forensic pathologists may however need to obtain a licence for the storage of relevant material if they take such material from a mortuary, or other licensed premises, to a location which is not covered by an appropriate licence.
63. To be covered by the licence granted in relation to premises the pathologist must either have been notified to the HTA by the designated individual (section 17(b)) or act under the direction of the designated individual or a person already licensed by virtue of section 17(c). It is suggested that most forensic pathologists should arrange

to have the licence applied to them under 17(b) at the mortuaries where they normally work.

64. The requirement for a licence may apply to others who store relevant material for analysis to determine the cause of death (unless covered by the section 39 exemption in relation to criminal justice purposes).

Advice

65. The Act (section 25) introduces criminal offences in relation to performing activities requiring a licence without such a licence (and by implication in violation of any condition on such a licence). The section includes the defence of reasonably believing that no licence requirement applies or that the activities are covered by a licence.
66. Pathologists are advised, when the relevant parts of the Act are implemented, to ensure the following:
- That any premises in which they perform post-mortem examinations have a licence;
 - That their activities are covered by a licence;
 - That any relevant material taken from the licensed premises are taken to licensed premises if the activity to be carried out there also requires a licence;
 - That they should send relevant material only to persons who are appropriately licensed (unless they practice in an area not subject to the provisions of the Act e.g. Scotland); and
 - That they comply with the conditions on any licence.

IMPLEMENTATION

67. The provisions of the Act will be introduced over a period of time. The arrangements have not been finalised but it is expected the provisions will be implemented as follows.
- The requirements for consent will become active from September 2006;
 - The offences with regard to consent will become active in September 2006;
 - The requirements with regard to licensing will become active from September 2006; and
 - The offences with regard to licensing will become active from September 2006.

FURTHER INFORMATION

68. Further information on this matter can be obtained from:

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SUMMARY

The summary sets out the application of the Act's requirements to those involved in the investigation of a death under suspicious circumstances where a post-mortem examination is undertaken on the authority of the coroner.

Activity	Requirements	Persons		
		Pathologist (activities related to determining the cause of death)	Pathologist (activities related to the investigation but not determination of the cause of death)	Others (e.g. mortuary staff or forensic scientists) involved in determination of the cause of death.
Examination at location where body found	Consent	Not Required [11]	Not Required [NWA]	Not Required [11]
	HTA Supervision	Applies [14 & 39(2)]	Not Applicable [NWA]	Applies [14 & 39(2)]
	HTA Licence	Not Required [39(3)]	Not Required [NWA or 39(3)]	Not Required [39 (3)]
Post-mortem examination, including removal of material	Consent	Not Required [11]	Not Required [NWA]	Not Required [11]
	HTA Supervision	Applies [14(1)(b) & 39(2)]	Applicable [14]	Applies [14(1)(b) & 39(2)]
	HTA Licence	Required [16 & 39(2)]	Required [16 and 39(2)]	Required [16 & 39(2)]
Examination of relevant material	Consent	Not Required [11]	Not Required [NWA]	Not Required [11]
	HTA Supervision	Applies [14(1)(b)]	Not Applicable [NWA]	Applies [14(1)(b)]
	HTA Licence	Not required [16(2)]	Not Required [NWA]	Not required [16(2)]
Storage of relevant material	Consent	Not Required [11]	Not Required [NWA]	Not Required [11]
	HTA Supervision	Applies [14(1)(d)]	Not Applicable [NWA]	Applies [14(1)(d)]
	HTA Licence	Required [16(2)(e)]	Not Required [NWA]	Required [16(2)(e)]

Disposal of relevant material ¹	Consent	Not Required [NWA]	Not Required [NWA]	Not Required [NWA]
	HTA Supervision	Applies [14(g)]	Does not apply [39(1)]	Applies [14(g)]
	HTA Licence	Not Required [16(2)]	Not Required [NWA]	Not Required [16]

NWA - Indicates not brought within the Act

¹ See paragraph 49.