



**Protocol to ensure the provision of forensic pathology services in the event of regulatory action taken by the Human Tissue Authority in England and Wales**

Version: 2.4

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Approved by:

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Next Review: September 2014

This Protocol is entered into between the:

- A. Association of Chief Police Officers of England, Wales and Northern Ireland (ACPO)
- B. Human Tissue Authority (HTA)
- C. Pathology Delivery Board (PDB)

**Institutional Background**

1. ACPO is an independent, professionally led strategic body. ACPO, in association with the College of Policing leads and coordinates the direction and development of the police service in England, Wales and Northern Ireland. In this protocol the phrase “Chief Officers of Police” refers to the Chief Constables in England, Wales, Northern Ireland and the Commissioners of Police for the City of London and for the Metropolitan.

2. The HTA was established by Section 13 of the Human Tissue Act (the HT Act) and is responsible for the regulation, through licensing and inspection, of establishments in England, Wales and Northern Ireland where post mortem examinations take place.

3. The PDB was established by the Home Secretary and contains members drawn from ACPO (National Police Lead for Forensic Pathology), Home Office, Coroners Society, British Association in Forensic Medicine, the Crown Prosecution Service and the Forensic Science Regulator. It is responsible to the Home Secretary for overseeing the forensic pathology service for the criminal justice system in England and Wales.

### **Regulatory Framework**

4. Under section 14 of the HT Act, the HTA's remit includes the storage and use of a deceased person's body and the storage, removal and use of material from a deceased person's body for scheduled purposes, including determining the cause of death. This includes post mortem examinations undertaken on the instruction of and for the purposes of the coroner (Section 39 (2)). However, section 39 (1) of the HT Act exempts from the HTA's remit and the licensing requirements of the Act anything done for purposes related to the prevention or detection of crime or the conduct of a prosecution.

5. Forensic Pathology is a service provided to the Coroners and Police in England and Wales to investigate violent or suspicious deaths. Forensic Pathologists work within a regional group practice independent of the Police Service and Home Office and are Registered by the Home Office and referred to as 'Home Office Registered Forensic Pathologists' (HORFP). All HORFP's are required to comply with the latest version of the Code of Practice and Performance Standards for forensic pathology in England, Wales and Northern Ireland.. They may be self-employed, in partnership or employees of an NHS Health Trust, University or commercial forensic provider. Members of the Register perform post mortem examinations in a number of facilities operated by the local authority, the NHS or, potentially, the private sector. Currently, members of the Register are not prevented from being a 'Designated Individual' under the Act.

6. The HTA has the power to revoke or vary a licence if it is satisfied that:

- i. Any information given for the purpose of the application was false.

- ii. The Designated Individual has failed to discharge their duties.
- iii. The Designated Individual is incapable of discharging their duties.
- iv. The licensed premises are no longer suitable for the licensed activity.
- v. The licence holder is no longer a suitable person to be a licence holder.
- vi. The Designated Individual is no longer a suitable person to supervise the licensed activity.
- vii. The Designated Individual dies.

7. The HTA has the power to suspend a licence where it has reasonable grounds to suspect that there are grounds for revoking a licence and is of the opinion that the licence should be immediately be suspended.

8. In exercising the power to revoke or vary a licence, the HTA has to give the licence holder and the Designated Individual notice of the proposed revocation or variation and is required to wait 28 days to allow the person to whom the notice has been sent to indicate if they wish to make representation.

9. No prior notice or warning is required by the Act in respect of suspension. The licence can only be suspended for up to three months at a time and in each case the duration of the suspension will be specified in the notification of suspension. The effect of the suspension is that the licences will be of no effect while a notice of suspension is in force, so licensable activities cannot take place during this period.

## **Commitments**

10. Due to the implementation of the Coroners and Justice Act, 2009, and the repeal of Section 22 of the Coroners Act 1988, the law regarding the movement of bodies across coronial areas is no longer restricted and therefore previous provisions of this Protocol in respect of contingency planning for the closure of mortuary facilities for forensic cases is

no longer relevant. Bodies can now lawfully be transported without restriction to alternative mortuary facilities with the consent of coroners in the event of the usual premises not being available. Mortuary facilities could be rendered unavailable for one or more of the following reasons:

- i. A key member of the Group practice no longer being available for service provision
- ii. Regulatory action taken by the HTA
- iii. Action taken by other regulators
- iv. Action taken by the operators of the facilities
- v. Damage to or destruction to the facilities

11. The PDB agrees to notify the HTA, under the Board's Suitability Rules, if a member of the Register, who is also a Designated Individual, is referred for consideration of a matter to the Review Committee and/or subsequently referred by the Review Committee to a Disciplinary Tribunal..

12. The HTA agrees that if it identifies a serious cause for concern that could lead to a suspension of the licence in a mortuary facility used by forensic pathologists, or that requires immediate suspension of licence, prior to any significant regulatory action being taken, immediate contact is made with:

- i. the Chief of Police in the area
- ii. the Secretary of the PDB
- iii. the relevant Coroner
- iv. the establishment's Chief Executive Officer

The objectives would be: (i) to undertake an impact assessment to inform the decision and actions taken by the HTA and ensure that they are proportionate and risk based, and (ii) to instigate activation of the contingency plan for that area, where relevant.

13. In the event of 12 above, the HTA, PDB and the relevant police force will consider the appropriate level of communications (given the possibility of criminal investigation) required with the:

- i. Licence Holder
- ii. Designated Individual
- iii. Employer of the Designated Individual
- iv. Local Coroners in neighbouring areas whose business continuity plans may be impaired as a result of suspension of a mortuary facility
- v. Ministry of Justice – Coroners Division
- vi. Chief Officers of Police for neighbouring areas whose business continuity plans may be impaired as a result of suspension of a mortuary facility
- vii. Other Service Providers – University/Forensic Science Providers/NHS Trust/Local Authority
- viii. Department of Health/Welsh Assembly Government
- ix. Forensic Science Regulator
- x. Local Authority as a Health & Safety authority
- xi. Health & Safety Executive
- xii. Medicines and Healthcare Products Regulatory Agency

14. Where the HTA suspects the possibility of a criminal offence under the HT Act, it will act in accordance with its Protocol for managing potential criminal breaches of Human Tissue legislation and seek guidance from the police to ensure as far as possible the protection and preservation of evidence.

15. If any criminal offences under the HT Act are alleged at facilities used for forensic post mortem examinations in any force area, ACPO & the PDB will take measures to avoid the risk of the impression of a conflict of interest or damage to working relationships; and consideration should be given to passing the investigation to another force, or division of the force.

16. For the avoidance of doubt, the parties to this protocol do not intend to create legal relations or a legally binding contract, by agreeing to this protocol and remain free to exercise their respective powers, unfettered by the terms of this protocol.

### **Human Tissue held under Police Powers**

17. Between 2010 and May 2012, ACPO lead a national audit of human tissue held by police forces in England, Wales and Northern Ireland following homicide and suspicious death investigations. ACPO and the Home Office (then NPIA) identified that there was a problem with unnecessary retention of tissue and issued recommendations to prevent future unnecessary retention. One such recommendation was that a *“review of police exhibits held on HTA licensed premises should be included within the regular HTA inspection process with a mechanism for reporting back to the police and the Home Office”*. It is intended that police held human tissue should therefore be included within the HTA regular inspection process, albeit such material is excluded by virtue of Sect 39 of the Human Tissue Act.

18. The HO does not require the HTA to prioritise for inspection, mortuaries that are holding material for the police. Therefore, the HTA inspection programme of inspections will continue as scheduled.

19. The HTA will confirm at inspection planning stage that an establishment is storing material for the police on HTA-licensed premises; this can be done by the Regulation

Manager at their initial contact with the Designated Individual (DI). If the DI confirms that material is being stored for the police, the Regulation Manager will do the following:

*Before the inspection*

- Find out the scale and location of the material stored; the HO will accompany the HTA to assist if the amount appears to be significant, and this can be determined on a case by case basis with the Head of Regulation;
- log the information in the establishment's folder on the HTA database;
- include inspection of these premises in the timetable to assess the suitability of the storage arrangements, in line with HTA standards on premises, facilities and equipment, as well as a traceability audit;

*During the inspection the HTA will;*

- review procedural documentation relating to retention, audit and disposal of police holdings, including mechanisms for chasing the police at intervals where tissue is held for long periods;
- check the establishment's audits of retained material, including frequency and resulting actions;
- undertake an audit of selected samples, checking that paperwork in each case supports their continued retention;
- include questions about HO PMs in the meeting with the coroner or coroner's officer;
- provide any necessary advice and guidance;

*After the inspection the HTA will;*

- include reference to police holdings in the report, which will not change in format or substance and will not be provided to the HO.

20. If the Regulation Manager identifies 'shortfalls' in relation to police holdings, they will not take any regulatory action as these samples are outside the HTA's remit, but will refer these to the HO. Once provided with the information, the HO will liaise with the senior management teams of relevant forces and introduce mechanisms to deal with material where they are needed. There is no expectation that the HTA will follow up on

issues after informing the HO.

21. HTA inspection reports are published on its website; if any report induces an FOI in relation to police holdings, these will be referred to and dealt with by the HO on a case by case basis.

22. The Home Office will assist in any training and briefing of HTA Regulation Managers in respect of issues relating to police held exhibits, including relevant law and procedural considerations.

23. The Home Office will accompany HTA Inspectors in the early stages of inspection where police held material is known to exist. They will also accompany HTA Inspectors on such inspections when it is known or believed that significant or problematic police holdings are expected.

24. Any action in respect of police holdings which are outwith the responsibility of the HTA, including any disciplinary action deemed appropriate, will be taken forward by the Home Office and shall not be the responsibility of the HTA.

25. This protocol will be reviewed annually by the **PDB, ACPO and the HTA**. The PDB will be responsible for initiating this review.



Alan Pratt - Chair

Pathology Delivery Board



Debbie Simpson - Pathology Lead

Association of Chief Police Officers



Alan Clamp - Chief Executive

Human Tissue Authority



## DATE

<b>Version Number</b>	<b>Date Approved</b>	<b>Approved By</b>	<b>Brief Description</b>
1.0	07/12/2011	Pathology Delivery Board (PDB)	Final version written on 07/12/2011. Presented and approved by the PDB on 31/01/2012
2.0	25/02/2013	HTA / ACPO	Version reviewed by the Forensic Pathology Unit and small typographical amendments made.
2.1	24/04/2013	HTA	Signed by Alan Clamp HTA
2.2	16/08/2013	DJ	Updates and amendments by the FPU. Additions made by Rachel Webb
2.3/2.4	14/11/2013	DJ	Amendments regarding references to Police Authorities and addition of College of Policing