

Checklist - maintaining compliance with consent standards

Consent is the fundamental principle of the Human Tissue Act 2004 and underpins all licensed activity. This guidance provides practical steps to help establishments achieve compliance with consent standards C1 and C2, as detailed in Code A: Guiding Principles and Code B: Post-Mortem Examination.

Why this matters

Non-compliance with consent standards can cause distress to bereaved families, attract media attention and damage public confidence. The HTA may undertake remote assessment or onsite inspection where there are significant concerns about consent-seeking practices.

C1: Obtaining valid consent

Policy and procedures checklist

Ensure your consent policy covers:

- ☐ Who can seek consent (with appropriate training requirements)
- ☐ Who can give consent (avoid using 'Next of Kin' terminology)
- ☐ Removal of relevant material from the deceased
- ☐ Retention and future use of tissue
- ☐ Reference to HTA Codes of Practice (Code A and Code B)

Ensure your Standard Operating Procedure (SOP) includes:

- ☐ Who can seek consent and their training requirements
- ☐ Who can give consent for PM examination, removal and retention
- ☐ Information provided to those giving consent
- ☐ How relatives can change or withdraw consent
- ☐ Actions staff should take if informed of consent changes
- ☐ Consideration of relatives' emotional state when seeking consent

Review and update:

- ☐ Policies and SOPs reflect current practice
- ☐ Regular reviews are scheduled and documented

Information for families checklist

Ensure written information includes:

- ☐ Who can give consent (avoid 'Next of Kin' terminology)
- ☐ Clear options for handling tissue after PM examination (repatriation, return for burial/cremation, disposal, storage)
- ☐ What happens if no decision is made
- ☐ If tissue is retained for future use, explain potential uses
- ☐ If material will be disposed of after a certain timescale
- ☐ How to change or withdraw consent
- ☐ Timeframe for changing minds (recommend 24 hours minimum, not less than 12 hours unless specifically agreed and documented)
- ☐ Contact details for questions or changes

Make information accessible:

- ☐ Available in different languages and formats
- ☐ Access to interpreters/translators arranged when needed
- ☐ Opportunities provided for families to ask questions

Consent form checklist

Ensure consent forms:

- ☐ Are agreed and ratified by your establishment
- ☐ Are based on HTA model forms or (for infants) Sands resources, or (in Northern Ireland) Department of Health NI standardised forms
- ☐ Record consent for PM examination separately from retention and future use
- ☐ Record separate consent for removal and storage of organs and tissue for scheduled purposes
- ☐ Are regularly reviewed for currency
- ☐ Are the latest version if using forms from another establishment

C2: Training and competency

Training requirements checklist

Ensure consent seekers:

- ☐ Have completed up-to-date training addressing the HT Act and Codes of Practice
- ☐ Are aware of local policies and SOPs
- ☐ Have training appropriate to their role (adult and/or paediatric/perinatal)
- ☐ Receive refresher training (recommend not exceeding three years)

Training records checklist

Maintain systems to:

- ☐ Record all consent training (internal or external)
- ☐ Keep third-party training records locally
- ☐ Maintain a list of consent-trained staff
- ☐ Identify when individual training is due to lapse
- ☐ Make records available to the Designated Individual and for HTA inspection

Consider:

- ☐ Limiting training to a core group (e.g. Bereavement Midwives, Medical Examiners, APTs) to maintain oversight

Competency requirements checklist

Ensure arrangements for:

- ☐ Untrained staff seeking consent are always accompanied by trained individuals
- ☐ This accompaniment is documented on the consent form

Competency assessment checklist

Establish processes to:

- ☐ Regularly review PM consent forms for completeness
- ☐ Record and act upon any discrepancies
- ☐ Address feedback from third-party establishments
- ☐ Align competency assessment frequency with training frequency
- ☐ Use appropriate assessment methods (e.g. direct observation, Q&A, online quizzes, peer review, consent form review)
- ☐ Ensure assessments are conducted by experienced, trained, competent consent seekers
- ☐ Maintain competency records for adult and paediatric/perinatal consent seekers
- ☐ Make competency records available to the Designated Individual and for HTA inspection