

**Human Tissue Authority consultation on Codes of Practice prepared
under the Human Tissue Act 2004: A rationale**

Introduction

This paper provides a summary of the responses received by the Human Tissue Authority (HTA) to its consultation on its first six Codes of Practice prepared under the Human Tissue Act 2004 (HT Act). It focuses particularly on the key messages which respondents to the consultation wished the HTA to consider when drawing up the final versions of the Codes of Practice.

Background

The HT Act 2004 received Royal Assent in November 2004 having received broad support in both houses of Parliament. The HT Act is a result of a comprehensive review of the law on the taking, storage and use of human tissue and organs that followed post mortems.

The HT Act includes provisions for Codes of Practice to be made by the HTA on a number of issues. The Codes are intended to form part of the regulatory system under the HT Act. Their purpose is to provide guidance to persons carrying out activities within the HTA's remit and to lay down the standards expected in the carrying out of such activities. The Codes provide detailed advice on the matters that they cover and include explanation of requirements under the HT Act and the Regulations.

Process

Under the HT Act, the HTA is required to undergo a consultative process before producing its Codes of Practice.

The HTA chose to carry out a very extensive process of consultation on the initial drafts of the first five codes – broader in fact than that proposed in the Cabinet Office consultation guidance – so providing a wide range of stakeholders with the chance to put forward their views in a number of different ways. The consultation process on the Codes of Practice was conducted over a 3-month period (July–October 2005).

In addition, the HTA held four consultation workshops in September 2005, attended by a range of professional and lay participants, in London, mid Wales, Belfast and Sheffield.

Sufficient time was provided for HTA members to discuss and debate the consultation responses, measure their views against other members' ideas, and discuss the content of the final drafts to go to Ministers at length and in depth.

The HTA considered very carefully the many comments they received and made its decisions on the final content to be included in the Codes of Practice based on the responses to the consultation together with agreement with HTA members.

The consultation on Code 2 strongly suggested that the Code on donation of solid organs should be separated from the one on bone marrow and peripheral blood stem cells (PBSCs) and the Authority agreed that this should be the case. A further consultation on Code 6 was conducted during a 2 week period in March to supplement the substantial responses on donation of bone marrow arising from the consultation on Code 2 (see Codes 2 and 6 below). It was important that Code 6 should be issued at the same time as the other five Codes so that guidance on donation would be comprehensive.

Response

A total of 117 responses were received. A wide range of stakeholders both individuals and organisations put forward their views, including coroners, crematoriums, doctors, health and non health organisations, hospitals, royal colleges, medical schools, universities and the general public.

A breakdown of respondent type and the number of responses received is shown below:

Number of responses	
Online responses	62
Email responses	40
Hard copy responses	15
Total	117
Types of respondents	
Coroner	2
Crematorium	2
Doctor (individual response)	2
Health organisation	45
Hospital	9
Hospital – pathology/histology units	11
Hospital – oncology unit	1
Medical School / University	16
Non Health Organisation	7
Public – group	12
Public – individual	4
Royal College	6
Number of Responses per Specific Code:	
Code 1	78
Code 2	40
Code 3	48
Code 4	35
Code 5	64

The overall response to the Codes was positive. While almost all respondents and workshop participants were able to suggest ways in which the Codes could be improved, there were no rooted objections to the HTA producing Codes of this nature, and the process of consultation was considered to be valuable.

The HTA would like to thank all those who took time to respond to the consultation. The consultation responses formed a valuable and helpful contribution to the HTA's understanding and interpretation of its remit.

Since a wide number of responses was received covering a broad range of areas, as expected, not all comments were taken into account. Following extensive revision, the Codes have now obtained final approval from Parliament.

The HTA will be interested to receive any feedback about how the Codes of Practice are being used as guidance and how they might be improved further. Based on these comments, a revision of the Codes will be considered in due course.

The key themes

The key themes that emerged from the consultation exercise were:

Code 1 – Consent

The overall number of responses received on this Code was 78, representing 67% of the total number of responses to the consultation. The key issues and how these were resolved are detailed below.

Hierarchy of Consent

A number of consultation responses highlighted potential problems in working with the hierarchy of consent set out in section 27 of the HT Act 2004. Section 27 of the HT Act lists people in a “qualifying relationship” to a deceased person, in order of precedence, who are eligible to give consent. It was acknowledged that this hierarchy may cause difficulties in the event of disputes between family members. The final version of the Code therefore aims to offer more guidance on how to manage disagreements amongst families.

Model Consent Form

There was support for a model consent form and model leaflets to support the consent process. It was considered appropriate for the HTA to produce guidance to shape local production, whilst taking into account the particular position in Northern Ireland. The format and number of consent forms to be produced by the HTA is still under discussion.

Commercial Involvement

Responses highlighted the need for patients to be made aware if their samples would or could be used for research involving the commercial sector. They should be given appropriate information on the range of activities and researchers which may be involved and whether these include commercial

pharmaceutical companies. The Code takes this into account and states that patients should be fully informed (Paragraph 80 of the Code).

Fetal Tissue

Although the number of responses received was relatively small, concerns were raised during the post-consultation period by the HTA about the status of, and issues around, fetal tissue and products of conception. Following discussion with the Department of Health and other stakeholders, the text was amended to reflect the different status of fetal tissue and products of conception, whilst still emphasising the underlying principle of consent (Paragraph 66 of the Code).

Code 2 – Donation of organs, tissue and cells for transplantation

The overall number of responses received on this Code was 40, representing 34% of the total number of responses to the consultation. The key issues and how these were resolved are detailed below.

Bone Marrow and Peripheral Blood Stem Cells (PBSCs) donation

There was a widely held view that donation of bone marrow and PBSCs needed to be separated from solid organ donation since different processes were involved. Professionals in the field emphasised the substantial difference, in terms of risk, between the transplantation of solid organs and regenerative tissue; and explained the rigorous procedures that were already deployed in transplantation of bone marrow and PBSCs. The HTA acknowledged these differences and agreed that a separate Code of Practice would better reflect the needs of the donors, recipients and clinical teams by drawing on current best practice. This Code was subsequently prepared (see Code 6 below) and a separate, additional, consultation process was held as explained in the 'Process' section above.

Donation of organs from children and adults lacking capacity to consent

It was considered that donation from these two groups was rare and should be considered with particular care because of the vulnerable nature of these two groups. Based on these responses, it was decided that the donation of organs from children and incompetent adults should be approved by a panel of the HTA and this was provided for in the HT Act 2004, (Persons who lack Capacity to Consent and Transplantations) Regulations 2006, with supporting guidance in the Code.

Code 3 – Post mortem examination

The overall number of responses received on this Code was 48, representing 41% of the total number of responses to the consultation. The key issue and how this was resolved is detailed below.

Model Consent Form

There was support for a model consent form and model leaflets to support the consent process. It was considered appropriate for the HTA to produce guidance to shape local production, whilst taking into account the particular position in Northern Ireland. The format and number of consent forms to be produced by the HTA is still under discussion.

Code 4 – Anatomical examination

The overall number of responses received on this Code was 35 representing 30% of the total number of responses to the consultation. The key issues and how these were resolved are detailed below.

Licensing

The concern was mainly about who the Designated Individual (DI) should be. Section 17 of the HT Act specifies that a licence granted by the HTA shall designate an individual as the person under whose supervision the licensed activity is authorised to be carried on. The general view was that the DI should be an anatomist – this was agreed by the HTA, and the wording in the Code reflects this decision. It was also agreed that there was no need for all anatomy teachers or others supervising dissection to be DIs. These could be named on the licence instead. A practicable model therefore would be to have, for example, the Head of Anatomy as the DI and – if desired – all others supervising or teaching named on the licence.

Time limit for retention of bodies

There was debate over whether there should be a fixed time limit or a more flexible approach should be adopted. It was agreed by the HTA that two options should be built into the consent-making process – consent to retention for an indefinite period and the other consenting to retention for a longer period. This was subsequently reflected in the Code.

Code 5 – The removal, storage and disposal of human organs and tissue

The overall number of responses received on this Code was 64, representing 55% of the total number of responses to the consultation. The key issues and how these were resolved are detailed below.

Disposal of identified existing holdings

Section 9 of the HT Act defines an existing holding as the body of a deceased person, or relevant material which has come from a human body, held for a scheduled purpose immediately before the day the provisions in the HT Act relating to consent (Section 1(1) of the HT Act) come into force. The responses to consultation were varied and forceful on this topic, as were contributions to the Sheffield consultation workshop. The handling of existing holdings contains obvious potential for distress and damage to public confidence. There was discussion around what principles the HTA should

adopt in dealing with identified existing holdings and about making fresh contact with the families involved.

Specific proposals which were agreed following consultation relating to existing holdings, and reflected in the Code, were:

Existing Holdings – Unidentifiable: It was agreed that Trusts should be able to dispose of this material once the moratorium¹ was lifted in the same way they dispose of material currently. It was noted that the Code should include an explanation of what would be considered respectful disposal. Appendix A of the Code provides guidance on the disposal of existing holdings.

Existing Holdings – Identifiable and family has made contact: It was agreed that Trusts should continue to hold this material until further contact was made by the family. It was noted that there could be exceptional circumstances, such as health and safety issues, which would require disposal and in these cases it would be for the Trust to decide how to proceed but the principle would be to honour commitments made to the families.

Existing Holdings – Identifiable but no contact with the family: It was agreed that contact should not be initiated with families individually. The Code advises that Trusts should consider what additional publicity might be appropriate locally, and these holdings could be disposed of if no contact was made by the families in the 12 months following the lifting by DH of restrictions on the disposal of existing holdings (which will coincide with the publication of this definitive version of the Code of practice).

Code 6 – Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

This Code was produced following comments arising from the consultation on Code 2. The universal view was that guidance on donation of bone marrow and PBSCs should be separate from that on solid organ donation. As explained above (see paragraph on 'Process'), a further consultation on Code 6 was conducted during a 2 week period in March 2006 to supplement the substantial responses on donation of bone marrow and PBSCs arising from the consultation on Code 2 (see Code 2 above).

¹ In 2000, the Chief Medical Officer conducted a survey of the extent of holdings of human organs and tissues. Organisations were asked not to dispose of such material before the survey and pending further consideration of respectful disposal. The Retained Organs Commission (ROC) lifted restrictions on certain categories of stored material (for example collections that were deteriorating and posed a health and safety risk), but when ROC ceased its activities in March 2004, organisations were advised that restrictions should still apply pending further guidance. The HTA's Code of Practice provides definitive guidance that will enable local decisions to be made about disposal with confidence, and for restrictions to be finally lifted.

Whilst the view of the field was that donation of bone marrow and PBSCs by children should be approved locally, Ministers decided that the procedure was not without risk and should be approved by the HTA.

Insurance

The main issue raised during the further consultation was that it was not necessary to include advice for potential adult donors to contact their insurance companies to assess whether their existing policies remain valid – providing at the time of arranging the insurance the person was not contemplating a donor procedure. Based on professional advice sought by HTA, it was agreed to remove this section in the Code, since there is a duty to disclose all information at the time the cover is arranged; and in view of the long-term nature of this cover, there is no need to subsequently advise changes in circumstances.