Regulatory Policy Committee

Code A: Guiding principles and the fundamental principle of consent; HTA Code B: Post Mortem Examination Code and Standards; Code C: Anatomical examination Code and Standards; Code D: Public display Codes and Standards; HTA Code F: Donation of Solid Organs and Tissue for Transplantation

Human Tissue Authority (HTA)

RPC rating: validated

This Opinion covers five small measures; for each, a brief description of the code, the changes made to them and the impacts are given in the table below. All five have an Equivalent Annual Net Direct Cost to Business (EANDCB) which rounds to zero. The proposals all cover updates to these codes and all revisions were scheduled to be implemented in April 2017.

Measure	Description	Impacts
RPC17-DH-HTA-3953-Code A: Guiding principles and the fundamental principle of consent	The HTA Consent Code A offers professionals guidance about how to inform people and their families about their options and seek consent for the use of organs, tissue and cells. Overall, the Code has been simplified. A number of elements have changed since the	The measure affects 243 main sites and 146 satellite sites, which the HTA licenses for organ donation and which are classified as businesses for BIT purposes. The HTA argues that there are no changes to regulatory scope or requirements; the changes are limited to simplification of guidance. Based on

	previous version.	standard reading speeds and ASHE data, it estimates a total annual refamiliarisation cost of £454 and a one-off transitional familiarisation cost of £12,714.
RPC17-DH-HTA-3954-HTA Code B: Post Mortem Examination Code and Standards	The HTA Code B: Post Mortem Examination Code of Practice and Standards offers professionals guidance about how to meet HTA requirements relating to post-mortem examination and the storage of bodies and tissue. Overall, the Code has been simplified. A number of regulatory requirements have been changed. These include the following: - Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff. - There are clear reporting lines and accountability. - Visiting / external staff are appropriately trained and receive an induction which includes the	This change affects 5 main sites and no satellite sites, which are licensed by the HTA for post-mortem examination and the storage of bodies and tissue and are classified as businesses for BIT purposes. The HTA notes that some provisions of the guidance have been changed, though it argues that these largely make previous informal advice more explicit. It estimates the total transition costs of familiarisation, reviewing governance systems and updating documentation at £1226. The new Code replaces longer and more complex existing documentation with which staff at licensed premises would need to familiarise themselves; the HTA estimates ongoing benefits of £12 per annum in total as a result.

	establishment's policies and procedures. - Systems ensure data protection, confidentiality and public disclosure (whistle-blowing). - There are systems to ensure that all untoward incidents are investigated promptly. - Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored.	
RPC17-DH-HTA-3955-Code C: Anatomical examination Code and Standards	The HTA Code C: Anatomical examination Code of Practice and Standards offer professionals guidance about how to meet HTA requirements relating to the use of human bodies and tissue for education and training. Overall, the Code has been simplified, and more detailed guidance has been added in a number of areas. These include the following: - Gaining donor consent - Loan arrangements and satellite sites - Charging and cost recovery, including	The change affects 33 main sites and 16 satellite sites, which have been licensed by the HTA for the purpose of using human bodies and tissue for education and training and are classified as businesses for BIT purposes. The HTA argues that most of the changes improve clarity and impose no new regulatory requirements. However, it notes that the change to guidance on transparency of charging and cost recovery may create an additional regulatory requirement for some sites, as a result of the need to update information provided to donors.

	transparency of this to donors - Frozen material	The HTA estimates transitional costs at £16,183, resulting from updates to information provided by donors and familiarisation with the new guidance. As the guidance replaces two longer and more complex guidance documents, the HTA also estimates a total annual benefit of £845, as a result of a reduction in the time taken for regular refamiliarisation with the guidance.
RPC17-DH-HTA-3956-Code D: Public display Codes and Standards	The HTA Code D: Public Display Code of Practice and Standards offer professionals guidance about how to meet HTA requirements relating to the display of bodies and body parts in museums and exhibitions. Overall, the Code has been simplified. A number of elements have changed since the previous version. These include the following: - Less emphasis on training staff on how to seek consent. - Added details about what falls within the scope of relevant material.	The change affects 20 main sites and 0 satellite sites. Some of these are arguably not businesses for BIT purposes, but have been included in the analysis on grounds of proportionality. The HTA argues that most of the changes improve clarity and impose no new regulatory requirements. However, it notes that the change to guidance on traceability may create an additional regulatory requirement for some sites, as a result of the need to update processes. It estimates transition costs totalling £11,711 due to familiarisation, process updates, and changes to

	- Added information on the de-accession of human remains, which sign-posts the reader to the relevant section of the Human Tissue Act. - Included a list of the governance documents expected for inspections. - Added a new section on the display of photographic images or films, which states the legal position and provides brief advice on filming, particularly aimed at Designated Individuals who are responsible for ensuring suitable practices are used in the conduct of licensed activities.	documentation. The HTA also estimates a total annual cost of £4,109, as a result of an increase in the time taken to manage traceability. This is partially offset by a reduction in the time taken for regular refamiliarisation with the guidance, giving a net annual cost of £3,737.
RPC17-DH-HTA-3957-HTA Code F: Donation of Solid Organs and Tissue for Transplantation	The HTA Code F: Donation of solid organs and tissue for transplantation offers guidance to practitioners working in the field of living organ donation, and deceased organ and tissue donation. Additional guidance given around statutory referral requirements has been updated to align with Montgomery Court case results, which mean that doctors must make patients aware of any 'material risks' involved in proposed treatments and reasonable	4 main sites (private hospitals that are licensed for transplantation) and 0 satellite sites The HTA estimates transitional costs of £2,799 as a result of familiarisation and changes to processes to meet new regulatory requirements. It estimates annual costs of £598, as a result of refamiliarisation and the ongoing requirement to discuss material risks and reasonable alternatives with patients.

	alternatives.	

Quality of submission

The assessments are clear and concise, and provide appropriate evidence in support of a zero EANDCB in each case. The assessments would be improved by setting out clearly the implications of each set of guidance, and by explaining more clearly that business benefits should exceed costs for any changes made to business practices as a result of reading the guidance. Where the regulatory requirement imposed on business has changed as a result of the changes, the HTA should set out the evidence underpinning its assumptions; given the small number of businesses affected in each case the RPC is nevertheless able to validate a zero EANDCB.

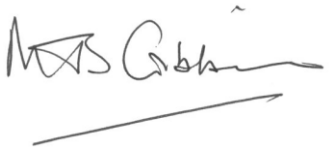
Departmental assessment

Classification	All Qualifying regulatory provisions
Equivalent annual net cost to business (EANDCB)	All £0.0 million
Business net present value	All £0.0 million

RPC assessment

Classification	All Qualifying Regulatory Provisions

EANDCB – RPC validated[1]	All £0.0 million
Business Impact Target (BIT) Score[1]	All £0.0 million



Michael Gibbons CBE, Chairman

[1] For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000.