

## **Human Tissue Authority's response to the Health and Social Care Information Centre consultation on the Records Management Code of Practice**

**January 2015**

### **Introduction**

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Health and Social Care Information Centre's (HSCIC) consultation on the Records Management Code of Practice.
2. The HTA is a specialist regulator committed to working with its stakeholders to ensure that human tissue and organs continue to be stored and used safely, ethically, and with proper consent, and that the bodies of deceased people are treated with dignity and respect.
3. The draft Records Management Code of Practice is an excellent articulation of the requirements for individuals and organisations, but we are of the view that the document would benefit from the addition of more detailed guidance on the collection and retention of data relating to tissues and cells. Accordingly, we have provided suggested wording which we propose should be added to the final document.
4. A core aspect of the HTA's role is to provide sector-specific codes of practice which provide practical guidance on human tissue legislation. The HTA is fully supportive of HSCIC's proposal to provide links to these documents within the Records Management code where further information may be required.
5. Additionally, we note that HSCIC is aware of the updates to be made to the Royal College of Pathologists' guidance on records retention, which should inform future iterations of the Records Management code.

## Comments on the draft documents

### NHS Code of Practice part 1

6. We would welcome the inclusion of an additional section at Annex C on the data to be retained by hospital tissue establishments or establishments using human tissue and/or cells, as covered by EU Directive 2006/86/EC. We would suggest the following wording for this section:

*Information on the minimum donor/recipient data set to be kept as required in Article 9 – EU Directive 2006/86/EC*

*A: By tissue establishments*

*Donor identification*

*Donor identification that will include at least:*

- *Identification of the procurement organisation or tissue establishment*
- *Unique donation ID number*
- *Date of procurement*
- *Place of procurement*
- *Type of donation (e.g. single or multi-tissue; autologous or allogeneic; living or deceased)*

*Product identification that will include at least:*

- *Identification of the tissue establishment*
- *Type of tissue and cell/product (basic nomenclature)*
- *Pool number (if applicable)*
- *Split number (if applicable)*
- *Expiry date*
- *Tissue/cell status (i.e. quarantined, suitable for use etc.)*
- *Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells having an effect on their quality and/or safety*
- *Identification of the facility issuing the final label*

*Human application identification that will include at least:*

- *Date of distribution/disposal*
- *Identification of the clinician or end user/facility*

*B. By organisation responsible for human application*

- a) *Identification of the supplier tissue establishment*
- b) *Identification of the clinician or end user/facility*

- c) *Type of tissues and cells*
- d) *Product identification*
- e) *Identification of the recipient*
- f) *Date of application*

7. We would welcome a section that refers to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 which introduced the requirement to keep raw data for 10 years and traceability data for 30 years (for HTA licenced establishments) to meet the standards set by 2006/86/EC Annex 1 E 7 and Annex V.

**NHS Code of Practice Part 2**

8. Under the Health Records retention schedule, we propose the following additions:

- Under ‘Donor records (blood and tissue)’ that ‘2006/86/EC and Human Tissue (Quality and Safety for Human Application) Regulations 2007’ is added
- That between ‘Photographic records’ and ‘Records of telephoned reports’, an additional row is added as follows:

| <b>Type of health record</b>       | <b>Minimum retention period</b>   | <b>Derivation</b>       |
|------------------------------------|---|-------------------------|
| Raw data (Human tissues and cells) | 10 years – raw data, which are critical to the safety and quality of the tissues and cells shall be kept so as to ensure access to these data for at least 10 years after expiry date, clinical use or disposal | EU Directive 2006/86/EC |

- That between ‘Temporary Residents’ Forms (GMS 3/99)’ and ‘Transplantation records’, an additional row is added as follows:

| <b>Type of health record</b>        | <b>Minimum retention period</b>   | <b>Derivation</b>                             |
|-------------------------------------|---|---|
| Traceability Records (Human Tissue) | Required to trace human tissues or cells from donor to recipient. 30 years from expiry date, disposal or clinical | EU Directive 2006/86/EC Art 9(2) and Annex VI |

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We would welcome the opportunity to discuss any of the suggestions made in this response if required.