Research Code and Standards

Department for Health – Human Tissue Authority

RPC rating: validated

Description of proposal

The Human Tissue Authority (HTA) Research Code of Practice and Standards offers professional guidance on how to meet HTA requirements relating to the use of human tissues for research.

The code and standards were first issued in 2006 and were updated in 2016. The code has been revised following a review. The changes in requirements are minor, but the documents have been restructured and more sector-specific guidance has been added.

The regulator states that there are no changes in process or policy resulting from the update in Research Code and Standards.

The revised codes and standards will be implemented in April 2017.

Impacts of proposal

The HTA licences cover 161 main research sites and 138 satellite sites; of those 137 main sites and 114 satellite sites are classified as businesses for BIT purposes. Therefore 251 sites in total are in scope for BIT.

The Department has estimated a one-off transactional cost of £60,000 for the 251 sites. This includes familiarisation costs of £8,000.It also includes administrative costs, totalling £52,000, to some establishments whose internal documentation must be updated to reflect updated references to the Research Code and Standards.

There will also be an ongoing cost of £4000 per annum, as some staff at each site will need to read and refer to the additional text in the course of their work.

The guidance will incorporate two of the old standalone Codes, which means that staff will no longer have to read the previous Disposal Code or the Import and Export Code. This will create a total annual benefit of £7,000 across the 251 sites.

The regulator also notes that the Standards have been set out explicitly in its licence application form. Although this change increases the length of the form and the overall time required to read it, the regulator argues (plausibly) that it also makes the form clearer and easier to complete, and that the net impact of the change is therefore negligible.

Quality of submission

The costs and benefits of this very small measure are clearly described and proportionately evidenced. The structured approach to considering and presenting costs and benefits is an example of good practice, as is the brief comment on sensitivity towards the end of the assessment. Given the very small scale of the measure, it might have been possible to present a still briefer analysis which was nevertheless fit for purpose – perhaps framed around the break-even calculations which the regulator has clearly carried out.

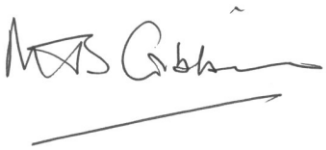
Departmental assessment

Classification	Qualifying regulatory provision (IN)
Equivalent annual net cost to business (EANCB)	Zero
Business net present value	-0.03

RPC assessment

Classification	Qualifying regulatory provision (IN)
EANCB – RPC validated[1]	Zero
Business Impact Target (BIT) Score[1]	Zero
Small and micro business assessment	Not required (fast track low-cost regulation)

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



Michael Gibbons CBE, Chairman