
HFEA Code of Practice Update April 2017

Human Fertilisation and Embryology Authority (HFEA)

RPC rating: validated

Description of proposal

The HFEA's code of practice is reviewed twice a year, to ensure that it is still relevant to the fertility sector. The assessment covers revisions from April 2017, affecting guidance on:

- Legal parenthood
- Mitochondrial donation
- Egg sharing arrangements
- Consent to storage
- Storage periods

It also covers some trivial and mechanical amendments, such as the addition of external links, correction of minor typographical errors and changes to ensure consistency across all guidance notes.

In addition, the HFEA has made some changes to consent forms, including:

- Introducing a simpler posthumous birth registration form, to make it simpler for clinic clients to consent to become parents posthumously. This change has been made at the request of clinics;
- Introducing a suite of gender-neutral forms for transgender clients, which, aside from the issue of gender, are identical to existing forms;
- Minor amendments requested by the sector (for example, removing unnecessary signature boxes).

HFEA notified all licensing centres in advance about the updated policy through HFEA's e-newsletter.

Impacts of proposal

The UK fertility sector is small (with 132 active clinics and research establishments) and includes both public and private sector organisations. HFEA estimates that 95

clinics and research establishments carry out private work, based on data from its licensing regime. Thus it assumes that 95 businesses are affected.

HFEA argues that the revisions to guidance are clarificatory and the changes to forms exchange one form for another of similar scale, so that the main costs of the changes arise from familiarisation. It uses a standard cost model to estimate the costs to clinics of familiarisation and reviewing documentation. It has tested this model with a group of representatives of licensed clinics, who confirmed that it was broadly correct. It estimates that minor changes to guidance, where there are not any changes to practice, will cost 1 staff day per clinic. Moderate changes to guidance, which require some small alterations to practice, are assumed to cost between 2 to 10 staff days.

In this case, HFEA assumes that the impacts of the changes are moderate, and has calculated a range of costs based on 2, 5, and 10 days of familiarisation per clinic. In each case, the EANDCB is less than £50k and therefore the EANDCB and BIT score round to zero.

The RPC verifies the estimated equivalent annual net direct cost to business (EANDCB) of £0.0 million. This will be a qualifying regulatory provision.

Quality of submission

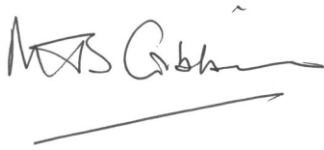
The submission is clear and provides enough information to support its estimate of the cost to business of the measure. HFEA has made different estimates of the familiarisation costs, based on more than the required number of clinics familiarising themselves with the guidance. It provides some views about indirect costs, even though these are not used in the calculation of the impact. It gives a clear explanation of the assumptions used.

Departmental assessment

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

RPC assessment

Classification	Qualifying regulatory provision
EANDCB – RPC validated ¹	£0.0 million
Business Impact Target (BIT) Score ¹	£0.0 million
Small and micro business assessment	Not required



Michael Gibbons CBE, Chairman

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