

## Medical Research Council and Wellcome Trust joint response to the Human Tissue Authority consultation on proposed new licence fees for research

Question 1: What impact, if any, will the proposed changes to the licence fee have on your establishment or your sector? Please provide evidence if possible.

As funders of research, the MRC and Wellcome Trust welcome the opportunity to respond to the HTA's consultation on proposed new licence fees.

Whilst we are sympathetic to the rationale for this proposed increase in fees, and support the HTA's cost-recovery risk-based approach to regulation, we are concerned at the upward trend in fees, especially in a time of economic instability where efficiency savings are being made in a number of other areas.

We are also concerned that the fee increase may be a disincentive for smaller research organisations to store tissue collections to avoid the costs of licensing, and this may inadvertently compromise their research activity. However, it is of course difficult to provide firm evidence of this.

It is also worth noting that the five MRC research units that hold HTA licences pay these fees out of existing budgets, and expenditure on licensing obviously means that those monies cannot be spent more directly on medical research. Similarly for both the MRC and Wellcome Trust grant holders the research funder ultimately pays these fees. Again, monies that could be spent on research.

Question 2: The proposed fees have been calculated on a risk and activity-based model. Do you think that other factors should be taken into account?

As noted in our response to question 1, we support the HTA's cost-recovery risk-based approach to regulation. However, the fee structure could reflect other risk-based factors, perhaps using a two-tiered system in one or both of the following ways:

1. a greater fee for new licence applications, and a reduced fee for renewed licences; and/or
2. a greater fee for organisations with several licence conditions or inspection findings as these will incur additional inspections and work for the HTA, and a reduced fee for organisations with fewer conditions / findings.

Question 3: Do you have any other comments about the licence fee structure for your establishment or for your sector as a whole?

Please refer to comments contained in response to questions 1 and 2.