

## **Executive Note**

### **The Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006 SSI/2006/310**

The above instrument is being made in exercise of the powers conferred by sections 40(2)(c) and 48(2) of the Human Tissue (Scotland) Act 2006 (“the 2006 Act”). The instrument is subject to negative resolution procedure.

#### **Policy Objective**

Section 40 of the 2006 Act deals with the position of organs removed during a Procurator Fiscal post-mortem examination which takes place on or after the day on which 2006 Act comes into operation (1 September 2006). That section provides that where an organ has been retained as a result of a post-mortem examination instructed by the Fiscal it can be used for research, once no longer required for the Fiscal’s purposes, provided the research is approved by such person or persons or group or groups of persons as the Scottish Ministers may specify by order under section 40.

Section 48 deals with organs retained from a Fiscal post-mortem examination which takes place before 1 September 2006 and provides that these organs can continue to be used, without the need for authorisation under the 2006 Act, for the purposes of existing approved research, or for the purposes of education, training or new approved research. ‘Existing approved research’ and ‘new approved research’ for the purposes of section 48(1) means research which has been approved by such person or persons or group or groups of persons as the Scottish Ministers may specify by order under section 48(2).

The policy objective of this Order is therefore (a) to specify the person or persons or group or groups of persons who may approve research on organs removed during a fiscal post-mortem examination carried out on or after 1 September 2006 and (b) to specify such persons who may approve new research, or who may already have approved existing research, on organs removed during a fiscal post-mortem examination which was carried out before the Act came into force on 1 September 2006.

So far as these provisions relate to existing holdings of organs, they carry forward the arrangements put in place by the Review Group on the Retention of Organs at Post-Mortem, based on agreement with the 4 family support groups with which it was working. The arrangements, which reflected the strong support for research evinced by these groups, was that there should be a formal 5 year period from 18 April 2002 to 17 April 2007, during which families would be made aware of their entitlement to reclaim organs retained at post-mortem examination. Six months into that period, it would be possible to undertake research on such retained organs, provided that the research related to a significant topic, did not involve the total destruction of the organ and had Research Ethics Committee approval. Where the organs related to a Fiscal case, the research use would depend also on the agreement of the Fiscal office concerned.

The effect of specifying a Research Ethics Committee (REC) as the person who may approve research on organs removed either before or after section 40 of the 2006 Act comes into force is that research on such organs will only be able to be undertaken if it has REC approval. Further, in relation to ongoing research on organs which were removed during a post mortem

carried out prior to 1 September 2006, where that research is currently REC approved then re-approval by REC will not be required for that same research. RECs are the bodies responsible for approval of such research in the NHS and university spheres.

### **Financial Effects**

The instrument itself has no financial effects on the Scottish Executive or any other organisation.

### **Regulatory Impact Assessment**

The draft Order has no impact on businesses, charities or voluntary bodies. Hospital post-mortem examinations are already subject to the clinical standards devised by NHS Quality Improvement Scotland, and standards based on these are currently being developed for post-mortem examinations instructed by the Fiscal.

Health Department: Patients & Quality Division  
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