
SCOTTISH STATUTORY INSTRUMENTS

2006 No. 310

HUMAN TISSUE

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

<i>Made</i>	- - - -	<i>6th June 2006</i>
<i>Laid before the Scottish Parliament</i>	- - - -	<i>7th June 2006</i>
<i>Coming into force</i>	- -	<i>1st September 2006</i>

The Scottish Ministers, in exercise of the powers conferred by sections 40(2)(c) and 48(2) of the Human Tissue (Scotland) Act 2006(1), hereby make the following Order:

Citation, interpretation and commencement

1.—(1) This Order may be cited as the Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006.

(2) In this Order—

“the Act” means the Human Tissue (Scotland) Act 2006; and

“appropriate Research Ethics Committee” means—

- (a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(2); or
- (b) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State or the Scottish Ministers.

(3) This Order shall come into force on 1st September 2006.

Persons who may approve research on organs to which section 40 of the Act applies

2. The person (or persons), or group (or groups) of persons specified for the purposes of section 40(2)(c) of the Act is an appropriate Research Ethics Committee.

(1) 2006 asp 4.
(2) S.I.2004/1031.

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Persons who may have approved existing research and may approve new research on organs to which section 48 (1) of the Act applies

3. The person (or persons), or group (or groups) of persons specified for the purposes of section 48(2) of the Act is an appropriate Research Ethics Committee.

St Andrew's House, Edinburgh
6th June 2006

LEWIS MACDONALD
Authorised to sign by the Scottish Ministers

EXPLANATORY NOTE

(This note is not part of the Order)

Current practice as regards approval to carry out research on any organ removed from a deceased person is that the Research Ethics Committees (“RECs”) provide independent advice and approval on the extent to which proposals for any research studies comply with recognised ethical standards. Specifying RECs in the Order as being the person (or persons), or group (or groups) of persons who is to approve research carried out on organs removed either before or after the coming into force of the Human Tissue (Scotland) Act 2006 (“the Act”) (1st September 2006, by virtue of S.S.I.2006/251) therefore captures both the current and the intended ongoing role of the REC in considering all such cases in Scotland. Article 3 of the Order covers the position in relation to organs which were removed before the Act comes into force (both research which has already been approved as well as research which is still to be approved on such organs), whilst Article 2 provides for organs removed on or after the day on which the Act comes into force.

Organs removed on or after 1st September 2006: section 40 of the Act applies to organs removed during a fiscal post-mortem which is carried out on or after the day that section comes into force. Section 40(2) provides, in relation to such organs that they may be retained and used for education, training and research in certain circumstances where the organ is no longer required for procurator fiscal purposes. One of the criteria laid down in section 40(2)(c) relates to where the purpose in question is research, and this is that the research must be approved in writing by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order under that section. Article 2 of this Order therefore specifies an appropriate Research Ethics Committee (as defined in article 1) as the person (or persons), or group (or groups) of persons who is to approve research in order that the organ in question may be retained and used for the purposes of research in compliance with section 40(2).

Organs removed before 1st September 2006: section 48(1) of the Act, on the other hand, provides for organs already removed from the body of a deceased person during such a post-mortem which is carried out before the day on which section 40 of the Act comes into force and is held immediately before that day for use for the purposes of existing approved research (whether or not held then also for the purposes of the functions of the fiscal). The effect of section 48(1) is to ensure that such an organ may be retained and used after 1st September 2006, for the purposes of either the existing approved research, or for education, training or new approved research, without requiring new authorisation under the Act. For those purposes,

section 48(2)(a) of the Act defines “existing approved research” as meaning research approved before the day on which section 40 of the Act comes into force

section 48(2)(b) defines “new approved research” as meaning research approved on or after that day,

by such persons such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order.

Article 3 of this Order therefore specifies an appropriate Research Ethics Committee (as defined in article 1) as the person (or persons), or group (or groups) of persons who, in relation to existing research on an organ removed during a fiscal post-mortem carried out before the day on which section 40 of the Act comes into force is to have approved that research (thus reflecting that all existing research must have been REC approved and should accordingly not require to be re-approved), and who is to approve any research on such already removed organs after section 40

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comes into force in order that the organ in question may be retained and used for the purpose s of research in compliance with section 48(1).

This Order comes into force on 1st September 2006, being the date on which the Act comes into force.