



# THE SCOTTISH OFFICE

Department of Health

NHS  
MEL(1998)66

NHS Management Executive  
St. Andrew's House  
Edinburgh EH1 3DG

20th October 1998

Dear Colleague

## CLINICAL PROCEDURES INVOLVING XENOTRANSPLANTATION

### Summary

1. This letter announces Directions to the NHS with regard to the commissioning and provision of treatments involving xenotransplantation procedures. The Guidance enclosed with the Circular describes the arrangements under which clinical trials or procedures involving xenotransplantation may be undertaken, and the system for seeking approval to undertake such trials or procedures. The Guidance applies to the whole of the United Kingdom.

### Direction

2. The Direction made by the Secretary of State for Scotland is attached at Annex A.

### Background

3. Background notes on Xenotransplantation are attached at Annex B.

### Applications to undertake Clinical Trials

4. Details of the procedures for applying to undertake clinical trials involving xenotransplantation are contained in *Guidance on Making Proposals to Conduct Xenotransplantation on Human Subjects*, a copy of which is enclosed with this Circular.

Yours sincerely

**DR KEVIN J WOODS**  
Director of Strategy & Performance Management

### Addressees

#### For action:

General Managers, Health Boards

Chief Executives, NHS Trusts

Chairmen, Local Research Ethics Committees

Chairman, Multi-Centre Research Ethics Committee for Scotland

#### For information:

General Manager, Common Services Agency

General Manager, State Hospitals Board for Scotland

General Manager, Health Education Board for Scotland

Executive Director, SCPMDE

### Enquiries to:

Miss K Glancy  
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St Andrew's House  
EDINBURGH EH1 3DG

Tel: 0131-244 2544  
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Date	

## Background

1. Xenotransplantation is defined as any procedure that involves the use of live cells, tissues and organs from a non-human animal source, transplanted or implanted into a human or used for ex vivo perfusion.
2. The United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) was established in 1997 to regulate and oversee developments in xenotransplantation and to advise the UK Health Ministers on matters relating to xenotransplantation.
3. It is part of the UKXIRA's remit to advise the UK Health Ministers on "*the acceptability of specific applications to proceed with xenotransplantation in humans*". Any proposal to undertake a trial or procedure involving xenotransplantation in the United Kingdom should therefore first be submitted to the UKXIRA for consideration. NHS trusts should note that no trial or procedure should be allowed to proceed on NHS premises without the prior approval of the proposal by the Secretary of State.
4. Xenotransplantation can take a number of forms, including:
  - transplantation of animal organs (such as hearts, kidneys, livers);
  - cell therapies, such as the transplantation of pig neural cells and pig pancreatic islet cells;
  - use as part of a medical device, such as an extra-corporeal liver device utilising viable animal cells; or
  - the use of viable animal cells in gene therapies such as the use of murine cells.
5. Clinical trials or procedures, involving xenotransplantation, may therefore also require the approval or notification of the Medicines Control Agency (MCA), the Medical Devices Agency (MDA) or the Gene Therapy Advisory Committee (GTAC). In general, the first point of contact should be the UKXIRA Secretariat. For gene therapies, the first point of contact should be the Gene Therapy Advisory Committee. Contact details are below.
6. It should be noted that the use of animals in xenotransplantation research or as sources for clinical xenotransplantation requires appropriate authorisation under the terms of the Animal (Scientific Procedures) Act 1986.
7. Proposals to undertake research require Ethics Committee approval. Local and Multi-Centre Research Ethics Committees should ensure that no proposal for a clinical trial of xenotransplantation is considered unless it has first been approved by the UKXIRA.

8. All enquiries regarding UKXIRA, and applications to undertake clinical trials involving xenotransplantation, should be addressed to:-

The UKXIRA Secretariat  
Department of Health  
Room 313  
Wellington House  
133-155 Waterloo Road      Tel: 0171 972 4847  
LONDON SE1 8UG              Fax: 0171 972 4852

9. Enquiries involving gene therapies should be addressed to:-

The GTAC Secretariat  
Department of Health  
Room 534  
Wellington House  
133-155 Waterloo Road      Tel: 0171 972 4021  
LONDON SE1 8UG              Fax: 0171 972 4196