

NATIONAL HEALTH SERVICE

NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005

This version incorporates the following Amendment Directions:

- **NHS Blood and Transplant (England) (Amendment) Directions 2005**
- **NHS Blood and Transplant (England) (Amendment) Directions 2009**
- **NHS Blood and Transplant (England) (Amendment) Directions 2010**
- **NHS Blood and Transplant (England) (Amendment No.2) Directions 2010**
- **NHS Blood and Transplant (England) (Amendment) Directions 2011**
- **NHS Blood and Transplant (England) (Amendment) Directions 2013**
- **NHS Blood and Transplant (England) (Amendment) Directions 2015**

The Secretary of State for Health, in exercise of the powers conferred on her by sections 16D(1), 17 and 126(4) of the National Health Service Act 1977(a), and all other enabling powers, makes the following Directions—

Citation, commencement, interpretation and application

1.—(1) These Directions may be cited as the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005 and shall come into force on 1st October 2005.

(2) These Directions apply in relation to England.

(3) In these Directions—

“the Act” means the National Health Service Act 2006;

“NHS body” means **the National Health Service Commissioning Board, a clinical commissioning group**, a Special Health Authority, an NHS trust, an NHS Foundation Trust ;

“NHSBT” means the Special Health Authority known as NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG)(b); and

“the Schemes” means the following Donor Organ Sharing Schemes(c):

(a) Operating Principles for Pancreas Transplant Units in the UK, prepared by the UKT Kidney and Pancreas Advisory Group, first published in August 2003;

(a) 1977 c.49; section 16D was substituted by section 12(1) of the Health Act 1999 (c.8) (“the 1999 Act”) and amended by sections 1(3) and 3(1) and (2) of, and paragraphs 1 and 6(a) of Part 1 of Schedule 1 to, the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”); section 17 was substituted by section 12(1) of the 1999 Act and amended by section 1(3) of, and paragraphs 1 and 7 of Part 1 of Schedule 1 to, the 2002 Act and section 67(1) of, and paragraphs 5(1) and (3) of Part 1 of Schedule 5 to, the Health and Social Care Act 2001 (c.15) (“the 2001 Act”); section 126(4) was amended by section 65(2) of the National Health Service and Community Care Act 1990 (c.19), by paragraph 37(6) of Schedule 4 to the 1999 Act, by paragraph 5(13)(b) of Part 1 of Schedule 5 to the 2001 Act, by sections 6(3)(c) and 37(1) of, and paragraphs 1 and 10(a) of Schedule 8 to, the 2002 Act and by section 184 of, and paragraph 38 of Schedule 11 and Part 4 of Schedule 14 to, the Health and Social Care (Community Health and Standards) Act 2003 (c.43).

(b) Established by NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005, S.I. 2005/2529.

(c) Copies of the Schemes are available on the website www.uktransplant.org.uk

- (b) Operating Principles for Renal Transplant Units in the UK, prepared by the UKT Kidney and Pancreas Advisory Group, first published in May 1999;
- (c) Operating Principles for Liver Transplant Units in the UK and Republic of Ireland, prepared by the UKT Liver Advisory Group, first published in July 1999;
- (d) Operating Principles for Cardiothoracic Transplant Units in the UK and Republic of Ireland, prepared by the UKT Cardiothoracic Advisory Group, first published in May 1999; and
- (e) Operating Principles for Ophthalmic Transplant Units in the UK and Republic of Ireland, prepared by the UKT Ocular Tissue Advisory Group, first published in July 1999.

Functions in relation to blood, stem cells and tissue

2.—(1) In this paragraph, “blood, stem cells and tissue” means blood, blood components, blood products, plasma, stem cells and other tissue.

(2) In order to promote or secure the effective supply of blood, stem cells and tissue for the purposes of the health service, the Secretary of State directs NHSBT—

- (a) to provide a collection, storage and delivery service for blood, stem cells and tissue;
- (b) to provide a screening, testing and processing service for the preparation of blood, stem cells and tissue;
- (c) to conduct or commission research into the uses of and development of blood, stem cells and tissue;
- (d) to provide diagnostic and other services in connection with the collection and use of blood, stem cells and tissue and treatments depending on or requiring their use (including, for example, reagent preparation and provision, patient pathology and therapeutic services, histocompatibility and immunogenetic services, platelet and granulocyte immunology);
- (e) to promote, by advertising, marketing and otherwise, the donation of blood, stem cells and tissue, with a view in particular to maintaining an adequate supply of blood, stem cells and tissue;
- (f) to prepare, store and distribute plasma fractions and other products for therapeutic, diagnostic and other purposes;
- (g) to promote, through advice and guidance, the appropriate use of blood, stem cells and tissue (having regard in particular to the need to promote the effective use of blood) and, as it considers appropriate, to provide a reference laboratory for donors and patients; and
- (h) to establish and manage a register of blood and bone marrow donors and any associated services necessary for the effective treatment of patients.

Sale of blood products

2A.—(1) Where the exercise of the functions under paragraph 2(2) gives rise to blood components, blood products or plasma, other than whole blood which are not needed for the purposes of the health service (“surplus material”), then, except in the circumstances specified in sub-paragraphs (2) and (3), NHSBT shall consider selling those substances if it is reasonable to do so having regard, in addition to having regard to any guidance referred to in paragraph 6, to—

(a) financial, operational and reputational risks to NHSBT and the health service; and

(b) relevant guidance issued by Her Majesty’s Treasury.

(2) NHSBT shall not consider the sale of surplus material under sub-paragraph (1) where the purpose of the sale would be to supply anything which might be—

(a) administered to a person;

(b) used in the manufacture of a product which might be administered to a person;
or

(c) used as a supplement to a tissue culture medium.

(3) NHSBT shall not consider the sale of surplus material under sub-paragraph (1) unless any profit from the sale would be used for the purposes of the health service.

(4) NHSBT shall complete its consideration of the matters specified in sub-paragraphs (1) to (3) before it sells surplus material.

(5) This paragraph does not apply to supplies (whether by way of sale or otherwise) for the purposes of the health service.

Functions in relation to the transplantation of organs and tissues

3.—(1) In order to promote or secure the effective transplantation of organs and tissues for the purposes of the health service, the Secretary of State directs NHSBT—

- (a) to provide an organ and tissue matching and allocation service, having regard to the need to ensure the—
 - (i) maximum and most effective use of organs and tissues;
 - (ii) safety of persons and their survival rates; and
 - (iii) equity and integrity of the organ sharing system;
- (b) to maintain a list of persons who are in need of or are considered suitable for an organ or tissue transplant and to determine the criteria for inclusion on such list;
- (c) to consider and advise the Secretary of State and NHS bodies on ethical, legal and clinical issues which arise out of the organ and tissue donation and transplantation service;
- (d) to lead the development of donation and transplant standards and monitor the maintenance of such standards by NHS bodies;
- (e) to acquire, record, update and keep information about potential and actual donors and recipients of organs and tissues which are or may be available for transplantation and other related matters, and, having regard to the law relating to data protection and confidentiality, to make such information available;
- (ea) to acquire, record, update and keep information about persons who do not wish to donate organs and tissues for transplantation and other related matters and, having regard to the law relating to data protection and confidentiality, to make such information available;**
- (f) to analyse and audit the information acquired, recorded, updated and kept under sub-paragraph (e) **or sub-paragraph (ea)** above;
- (g) to promote, by advertising, marketing and otherwise, the donation of organs and tissues with a view to maintaining an adequate number of organs and corneas for transplantation;
- (h) to commission organ and cornea donation programmes in the health service;
- (i) to give advice about, or make arrangements for, the transport of organs;
- (j) to secure the provision of such education and training in any matter related to its functions under this paragraph as NHSBT considers appropriate, both to NHS staff and others;
- (k) to conduct or commission such research in connection with the field of organ donation and transplantation as NHSBT considers appropriate; and
- (l) to work within agreed reciprocal arrangements with other established organ exchange organisations in other countries, for the exchange of organs, where appropriate.

(2) For the purposes of sub-paragraph (1)(a), NHSBT may—

- (a) match and allocate organs and tissues from outside England; and

(b) to the extent that NHSBT carries out an equivalent service in relation to Scotland, Wales or Northern Ireland, in carrying out the organ and tissue matching and allocation service, have regard to the need to ensure the maximum and most effective use of organs and tissues, the safety of persons and their survival rates and the equity and integrity of the organ sharing system.

(3) The list maintained under sub-paragraph (1)(b) may be a list which includes persons in Scotland, Wales and Northern Ireland provided that the list indicates where the person is from.

(4) The information recorded, updated and kept under sub-paragraph (1)(e) may be recorded, updated, kept, analysed and audited with information about potential and actual donors and recipients of organs and tissues in Scotland, Wales and Northern Ireland provided that information indicates where the potential or actual donor or recipient is from or to which country the information relates.

(5) Where a potential donor has appointed one or more persons to represent him after death in relation to the donation of organs and tissues for transplantation and related matters, the information acquired, recorded, updated and kept under sub-paragraph (1)(e) may include information about up to two persons so appointed and that information may be recorded, updated, kept, analysed and audited with information about persons in other parts of the United Kingdom who have made such appointment.

(6) The information recorded, updated and kept under sub-paragraph (1)(ea) may be recorded, updated, kept, analysed and audited with information about persons who do not wish to donate organs and tissues in Scotland, Wales and Northern Ireland provided that information indicates where the person who does not wish to donate is from or to which country the information relates.

Functions in relation to the allocation of organs for transplantation

4.—(1) Subject to sub-paragraphs (2), (3) and (4) of this paragraph, the allocation of organs by NHSBT for the purposes of transplantation shall be in accordance with the Schemes.

(1A) When exercising functions in relation to the allocation of organs for the purposes of transplantation under paragraph 3(1) and sub-paragraph (1), NHSBT shall have regard to guidance issued by the Department of Health on the allocation of organs for the purposes of transplantation which is published before 30th March 2010 and, in order to give effect to that guidance, may allocate organs otherwise than under the Schemes.

(2) No person in Group 2 shall receive an organ for which there is a clinically suitable person in Group 1.

(3) Group 1 shall comprise—

(a) persons ordinarily resident in the United Kingdom;

(b) persons who are—

(i) members of Her Majesty's United Kingdom Forces serving abroad;

(ii) other Crown servants employed in the right of Her Majesty's Government of the United Kingdom having been recruited in the United Kingdom and who are serving abroad;

(iii) employees, recruited in the United Kingdom, of the British Council or the Commonwealth War Graves Commission and who are employed abroad;

or the spouse, **civil partner** or any child under the age of nineteen of any person falling within sub-paragraphs (i) to (iii) above;

(c) persons who are entitled under Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to medical treatment in the United Kingdom;

(d) persons entitled by virtue of a bilateral reciprocal health agreement or the European Convention on **Social and Medical Assistance** 1954 to medical treatment in the United Kingdom:

(e) **persons ordinarily resident in the Channel Islands.**

(4) Group 2 shall comprise persons who do not come within the categories of persons listed in Group 1.

General functions of NHSBT

5.—(1) NHSBT may exercise functions under—

- (a) section 12 of the Act (**Secretary of State’s arrangements with** other bodies); and
- (b) section 2(1)(b) of the Act (Secretary of State’s general power) to do anything whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of NHSBT’s functions.

(2) NHSBT, in performing the functions described in paragraph 2, 3 and 4 above, may provide advice and make recommendations to the Secretary of State on any matter connected with its functions.

Exercise of functions

6. NHSBT, in exercising its functions, shall have regard to any guidance issued by the Secretary of State.

Land transactions

7.—(1) Subject to sub-paragraphs (2) and (3) of this paragraph, NHSBT shall exercise the functions of the Secretary of State under section 211(1) to (3) (**acquisition, use and maintenance of property**) of the Act in so far as is necessary to enable it to secure and maintain such accommodation as it requires for the proper discharge of its other functions.

(2) The functions mentioned in sub-paragraph (1) do not include the powers of the Secretary of State to acquire land compulsorily.

(3) NHSBT shall not, without the prior approval of the Secretary of State, exercise the functions mentioned in sub-paragraph (1) so as to—

- (a) acquire or dispose of any land, or any interest in land, the value of which exceeds £1 million; or
- (b) acquire a leasehold interest where either—
 - (i) the term of the lease is less than one year and the rent payable exceeds £1 million; or
 - (ii) the term of the lease is not less than one year and the product of multiplying the number of years in the term by the amount of rent payable in the first year of the term exceeds £1 million.

(4) In sub-paragraph (3)(a) above “value” means the value on a disposal by sale with vacant possession on the open market.

(5) In sub-paragraph (3)(b) above “the term” in relation to a leasehold interest acquired by way of assignment means the unexpired term.

(6) Any function of the Secretary of State, under section 211 of the Act, shall be exercised in accordance with the procedures and instructions for the time being in force and issued by the Department of Health in the document entitled “Estatecode”(a), except in so far as such procedures and instructions are inconsistent with these Directions.

(7) Subject to NHSBT obtaining approval as and when required under sub-paragraph (3) above, where the exercise by NHSBT of any function to which these Directions apply requires—

- (a) the execution under seal of any document, NHSBT shall execute such document on behalf of the Secretary of State under its own seal; or

(a) Copies of this document are available on the website www.dh.gov.uk/estates

- (b) the execution of a document otherwise than under seal, NHSBT shall make arrangements for one of its officers who has been duly authorised for the purpose to sign the document for NHSBT on behalf of the Secretary of State.

Accounts

8.—(1) NHSBT must prepare and keep annual accounts in respect of each financial year which shall give a true and fair view of the income and expenditure and cash flows of NHSBT for the financial year, and the state of affairs as at the year end.

(2) The accounts shall be prepared in accordance with—

- (a) the Resource Accounting Manual(a);
- (b) the Department of Health Special Health Authority Manual for Accounts(b);
- (c) any other requests made by the Secretary of State,

except where agreed with the Secretary of State in which case the exception shall be disclosed in the notes to the accounts.

Annual report

9. The Secretary of State directs NHSBT to produce an annual report in respect of each year from 1st April to 31st March, covering its activities and finances (including officers' remuneration) and to submit that report to the Secretary of State by no later than 30th September each year, or by such other date as the Secretary of State may direct.

Revocation

10. The following directions are revoked—

- (a) The National Blood Authority Accounts Direction given on 19 March 1993;
- (b) The National Blood Authority Directions in relation to Powers of Income Generation given on 29 March 1993;
- (c) The National Blood Authority Directions in relation to Building and Engineering Functions given on 29 March 1993;
- (d) The National Blood Authority Directions in relation to Financial Management given on 5 April 1993;
- (e) The National Blood Authority (Land Transactions) Directions 1997 given on 23 July 1997;
- (f) The Directions on the Allocation of Human Organs for Transplantation given on 12 February 1996 in so far as they apply to United Kingdom Transplant(c).

Signed by authority of the Secretary of State for Health

Member of the Senior Civil Service
Department of Health

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- (a) This document is published by HM Treasury and is available on the website www.resource-accounting.gov.uk/current/frames.htm
 - (b) This document is available on the website www.info.doh.gov.uk/doh/finman.nsf
 - (c) United Kingdom Transplant was established by the United Kingdom Transplant (Establishment and Constitution) Order 1991, *see* S.I. 1991/407 as amended by S.I. 1996/971, 1998/1577 and 2000/1612, and abolished by the National Blood Authority and United Kingdom Transplant (Abolition) Order 2002, *see* S.I. 2005/2532.