

Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation

Guidance for transplant teams and Accredited Assessors

Contents list

Introduction

- Principles of the Human Tissue Act 2004
- The Human Tissue Authority
- Outline of regulatory framework and changes from previous arrangements

Section 1 – Accredited Assessor

- Introduction – role
- Accreditation – initial and ongoing
- Person specification
- Independence of the Accredited Assessor
- Role of the Accredited Assessor – cases which can be approved locally; cases that must be approved by the HTA
- Relationship with the HTA – delegated authority, advice and guidance
- Liability of Accredited Assessors
- Networks

Section 2 – Role of the Human Tissue Authority

- Introduction
- Referral to the HTA

Section 3 – Consent

- What is consent?
- Documentation of the consent process

Section 4 – Duties of the clinician responsible for the donor

- Donation
- Checklist for the clinician responsible for the donor

Section 5 – Duties of the Accredited Assessor

- Before the assessment – the referral process
- The assessment
- The report
- Queries
- Checklist for Accredited Assessors

Section 6 – Referral, assessment and approval processes

- Donation of Bone Marrow / PBSC from Adults Lacking Capacity
- Donation of bone marrow / Peripheral Blood Stem Cells from children who lack competence to consent

Section 7 – Documentation

- Form HTA RF (DC)
- Form HTA IT (DC)
- Form HTA IT (AA)
- Form HTA MD (DC)

Section 8 – Media policy

Appendices

- **Appendix 1** – Extract from England, Wales and Northern Ireland Regulations
- **Appendix 2** – Confidentiality
- **Appendix 3** – Scottish Annex

Introduction

Principles of the Human Tissue Act 2004

The Human Tissue Act 2004 (HT Act) sets out a new legal framework for the storage and use of human organs and tissue from the living and for the removal, storage and use of human organs and tissue from the deceased. The HT Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland – namely the Human Tissue (Scotland) Act 2006 – and the Human Tissue Authority (HTA) will perform certain tasks on behalf of the Scottish Executive. The HT (Scotland) Act has provisions on living donation almost identical to those in the HT Act. By agreement with the Scottish Ministers, the HTA will have responsibility for approving all forms of living donation involving Scotland.

The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons. The HT Act is intended to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole.

The Human Tissue Authority

The HT Act established the HTA as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for Scheduled Purposes set out in the HT Act.

As with the HT Act itself, the HTA intends to achieve a balance between the rights and expectations of individuals and families, and broader considerations like the importance of research, education, training, pathology and public health surveillance to the population as a whole.

One of the HTA's statutory functions is to issue Codes of Practice. These Codes give practical guidance to those carrying out activities which lie within the HTA's remit and lay down the standards expected.

The first set of Codes cover the following topics:

1. Consent;
2. Donation of organs, tissue and cells for transplantation;
3. Post mortem examination;
4. Anatomical examination;
5. Removal, storage and disposal of human organs and tissue;
6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.

From April 2006, the HTA has been the Competent Authority for the UK under the EU Tissues and Cells Directive (EUTCD)¹ for regulating human tissue banking for transplantation purposes. The main focus of licensing and inspection of banks holding tissue for this purpose have therefore been compliance with the safety and quality protocols that form part of the EUTCD.

Outline of regulatory framework and changes from previous arrangements

Currently, all assessments and approvals for donation of bone marrow and peripheral blood stem cells (PBSC) are made locally. Under the HT Act and the HT (Scotland) Act, donation of bone marrow and PBSC by children and adults competent to give consent (in Scotland, 'authorisation') will continue to be approved locally. The assessment must be supported by a declaration, signed by a senior member of the Bone Marrow Team (BMT) and kept in the case notes of the donor, that the principles and procedures in the HTA's Codes of Practice on the Donation of allogeneic bone

¹ 2004/23/EC

marrow and peripheral blood stem cells for transplantation and Consent have been properly applied. This declaration should be made readily available to the HTA upon request. Careful consent procedures should be adhered to by the person obtaining consent² to ensure that there is no infringement of best ethical processes.

Donations of bone marrow and PBSC from children who lack competence³ to give consent (in Scotland, all children), however, must be assessed by an Accredited Assessor and submitted to the HTA for approval. The decision was based on the need to give these potentially vulnerable donors a degree of protection by introducing an independent element into the decision-making process. This process would also apply in the very rare case when donation of bone marrow or PBSC is considered from adults who lack capacity to give informed consent.

In the case of donation by adults who lack capacity to consent, common law requires that prior to any assessment or procedure being undertaken, the decision for removal of bone marrow / PBSC must be referred to court for approval. For children who lack competence to consent, if there is any dispute between persons with parental responsibility or any doubt as to the child's best interests, the matter should be referred to court for approval. The best interest test itself raises difficult issues, particularly in the case of sibling donations from children who lack competence to give consent, as it involves principles of law and ethics. It is a non-therapeutic procedure for the donor and the need for the person with parental responsibility and the clinical team to balance the interest of one child against others in the family may lead to a conflict of interest and the dangers of wrong decision.

The HTA would then proceed to consider the case only if the court considered that donation was in the best interests of the donor and that the HTA's Codes of Practice had been properly implemented. The involvement of the HTA is to ensure that the interests of the donor have been properly considered. The need to refer cases to court does not apply to Scotland.

The relevant sections of the HT Act introducing the new processes in England, Wales and Northern Ireland and the equivalent provisions in the HT (Scotland) Act came into force on 1 September 2006 following Parliamentary approval of the commencement order and the relevant Regulations. An appeal mechanism is also in place for all potential living donors.

The position in Scotland regarding children and adults with incapacity is somewhat different, and the Scottish Executive has issued general guidance on such cases (see Appendix 3 – Scottish Annex).

² This will usually be a consultant or other senior member of the clinical BMT such as a senior psychologist or play therapist/specialist.

³ The assessment of 'competence' of the potential child donor should be determined by the unit.

Section 1 – Accredited Assessor (AA)

Introduction

Accredited Assessors (AAs) are usually, but not exclusively, based in hospitals with bone marrow transplant units. Once accredited by the HTA, they are able to act as the advocate for the donor and as representatives of the HTA to ensure the requirements of Section 33 of the HT Act are met (or Section 17 of the HT (Scotland) Act).

Accreditation

In order, to ensure that the relevant provisions of the HT Act in relation to bone marrow and PBSC were able to take effect by 1 September 2006, a two-stage accreditation process for Assessors was implemented.

The first stage involved an interim procedure, where an Assessor was deemed to be accredited if they had read and understood the Code of Practice on the Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation, in conjunction with the principles espoused in this guidance document.

Following this, a more substantive accreditation process took place as described below, and this is now the process that any potential new Assessors should follow in order to be accredited by the HTA.

The nominated individual is required to undertake a one-day training programme. Following satisfactory completion of this training, a certificate of accreditation will be issued and a letter of confirmation sent to the individual. A letter will also be sent to the Director of the transplant unit. This letter will confirm the AA's appointment and the facilities required to undertake the role including time built into their job plan / timetable, a room to see the donor, travel expenses if travelling to the trust to do the assessment, and payment by the BMT unit for translating services if required.

AAs will need to be reaccredited on an annual basis. Whilst the details of reaccreditation are currently being finalised it is likely that there will be two elements to the process: (1) formal 'refresher' training, possibly through an e-learning package; and (2) assessment based on the quality of reports received and whether there has been any feedback, complaints, appeals or adverse events relating to the AA.

Person specification

The AA can be one of the following and it is good practice that s/he is not a person who is directly involved with the procedure.

- Clinical nurse specialist
- BMT coordinator
- Social worker
- Psychologist
- Senior play therapist /specialist
- Currently registered with a professional body where appropriate for example GMC, NMC or equivalent
- No previous or pending disciplinary action within trust or professional body
- Completed designated training from the HTA
- Time available to assess the donor within a period agreed with the referring team according to clinical urgency and not exceeding one month from referral
- Good verbal and written communication skills.

Any individual wishing to be considered as an AA should contact the HTA for further information. Individuals seeking clarification about eligibility should also contact the HTA.

Independence of the Accredited Assessor

The HTA understand that, in assessing cases of bone marrow and PBSC, the AA will often be involved to a certain extent in the process. However, it is important to remember that the role of the AA is to act not only on behalf of the HTA, but also to serve as an advocate/guardian of the donor, to ensure that their rights have not been overlooked. Therefore, AAs need to maintain an element of detachment and objectivity in order to remain within the spirit of this Guidance.

If you are experiencing doubt as to whether you are able to act as an AA given your level of involvement in a given case, this is a good indication that you may not feel you can provide an objective assessment of the case and therefore should not act as the AA in that instance. The HTA recognises that this can sometimes be a difficult judgement to make on an individual case and it is important that any AA who feels uncertain should seek guidance from other AAs (see section on Networks below) and/or the HTA.

It is good practice, given these issues, that a unit/Trust have more than one AA that they can utilise to make it easier in cases where the AA is experiencing impartiality/objectivity issues. This will also be beneficial in case an AA falls ill or is on leave.

Role of the Accredited Assessor

There are two levels of approval; the first being local approval of donors who do not require AA assessment and the second where donors require AA assessment and subsequent HTA approval.

The AA should check with their unit, how far their role extends in terms of the assessment procedure, for example whether their role extends to private patients. Individual Trust policies will vary on this matter and the contractual obligations should be made clear by the Trust to the AA at the outset.

Cases which can be approved locally

All donations of bone marrow and PBSC by children and adults competent to give consent will continue to be approved locally in England, Wales and Northern Ireland. However, in Scotland, all donations by a child (that is, those under the age of 16) must be approved by an AA.

When the consultant or senior member of the BMT or donor registry team is satisfied that the requirements of the Code of Practice on the Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation has been met, s/he must complete:

- a consent form that includes a statement by the donor that s/he has received and understood sufficient information to give informed consent; and
- a declaration by the clinician that they have read and applied the code on Bone Marrow and PBSC as well as the HTA's code on Consent (see Section 7 – Documentation HTA - FORM HTA MD (DC)).

This consent and declaration can be on the same form and must be attached to the donor's notes before the bone marrow or PBSC harvest proceeds, and made available when requested by the HTA or a person or organisation acting on behalf of the HTA.

Cases that must be approved by the HTA

The following cases must be approved by the HTA, although it is envisaged that these cases will be infrequent – particularly those involving adults lacking capacity to give informed consent:

- where the donor is an adult who lacks capacity to give consent;
- where the donor is a child who lacks competence to give consent (in Scotland, all children).

From the records that are available, which cover the last three years preceding 2007, there were approximately 50 children a year who donated bone marrow/PBSC but lacked capacity to consent (chiefly in sibling donor situations). To date, there have been very few cases of donation from adults

lacking capacity. However, in the rare case where it may be necessary for an adult who lacks capacity to donate bone marrow or PBSC, a court must first consider if the donation would be in the best interests of the donor (see Introduction). Once court approval has been sought, these donations must be approved by the HTA (see Section 2 – Referral to the HTA). The need to refer the case of a child to court does not apply to Scotland.

Relationship with the Human Tissue Authority

The AA acts as a representative of the HTA. The HTA acts as a ready source of advice and guidance and should be contacted whenever required. Further details of situations where the HTA should be contacted are detailed in section 5 of this document.

Liability of Accredited Assessors

Although the AA acts as a representative of the HTA, many will be employed by their base hospital or stem cell transplant unit. Since it is envisaged that this work will be part of their NHS commitments it is expected that any liability will be borne by the individual's employer. In the case of:

- those who are retired, it is advised for governance purposes that they hold an honorary contract with the trust concerned; or
- those who work as an Accredited Assessor in the private sector should ensure they have the appropriate cover.

Networks

AAs are encouraged to make contact with Assessors in other units in their area, both to compare approaches to assessments and also to provide cover and mutual support where this is necessary. It is the responsibility of AAs to ensure that they use the network if they are concerned about any issue, or are uncertain about their paediatric experience/skills. The HTA will support such networks by providing contact details and further guidance that AAs may feel is necessary. In addition, AAs are encouraged to establish a communication link with the transplant team to facilitate the effectiveness of the assessment process. Contact with the stem cell transplant programme director or co-ordinator may be the best way to achieve this.

Section 2 – Role of the Human Tissue Authority

Introduction

Under the HT Act, the HTA have to be satisfied in all cases of living donor transplantation that the requirements of Section 33 of the HT Act have been met (Section 17 of the Human Tissue (Scotland) Act 2006).

Referral to the HTA

All reports (see attached template) should be faxed to the HTA executive at 0207 2113 430 clearly marked “BM/PBSC Donation”. In addition, a copy should be posted to the HTA at:

Transplantation Officer
Human Tissue Authority
Finlaison House
15-17 Furnival Street
London EC4A 1AB

A team dedicated to the approval of donations will consider the assessment submitted by the AA.

The AA may need to supply further information to the HTA in order for the final decision to be made. The HTA executive will communicate with the AA to request this additional information. This additional information may include among other items:

- Form HTA IT(AA) when an independent translator has been used
- A copy of the original referral letter/form from the clinician responsible for the donor.

Electronic referrals will be permissible once the HTA's infrastructure allows for this capability and Assessors have been fully accredited at an HTA training event. The HTA executive will make their decision within a maximum of 10 working days. On the rare occasion where there is a clinical reason for an immediate decision to be made, the HTA should be contacted by phone at 020 7200 3400 as much in advance as possible, so that the appropriate staff can be available to assess the submitted report and provide a final decision.

The decision will be communicated to the AA and clinician responsible for the donor by email, bearing the HTA case number (from the AA's report). The donation and subsequent transplantation cannot proceed without this approval.

Any enquiries can be addressed to the HTA secretariat via email at transplants@hta.gov.uk or 020 7211 3400.

Section 3 – Consent

3.1 What is consent?

Donation of bone marrow and peripheral blood stem cells is an expression of individual autonomy and altruism.

Consent is the legal expression of autonomy and the basis of the agreement to donate within the HT Act. The HT (Scotland) Act is worded in terms of 'authorisation', but this equates to consent under the 2004 Act.

For consent, to be valid the donor must:

- have capacity;
- be informed; and
- donate voluntarily.

Consent is an ongoing process delivered by appropriately qualified members of the relevant clinical team. The HTA considers it best practice that emphasis is placed on good preparation, to ensure that consent is provided in an informed and appropriate manner.

Consent for first and each repeat donation must be obtained before harvesting bone marrow, PBSC or lymphocytes from a donor for transplantation.

There are limits to consent. Approval by the HTA will be required for donation involving individuals (including children) who lack capacity to consent.

The position in Scotland regarding children and adults with incapacity is somewhat different and the Scottish Executive has issued guidance on these cases (see Appendix 3).

Please refer in addition to the HTA's Codes of Practice on Consent and the Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.

3.2 Documentation of the consent process

Clinical teams involved with donation of bone marrow, PBSC and lymphocytes will need to ensure that the Trust's policies on consent are compatible with the HTA and Codes of Practice. Whilst written consent serves as evidence of consent it should be remembered that if the elements of voluntariness, appropriate information, and capacity have not been satisfied then a signature on a form will not make consent valid.

Section 4 – Duties of the clinician responsible for the donor

For transplantation of bone marrow or PBSC, clinicians are advised to refer to the European Directives 2004/23/EC and 2006/19/EC. Also the Standards produced by the Joint Accreditation Committee (JACIE) are shortly to be re-issued, as a joint set of Standards in collaboration with the US Foundation for the Accreditation of Cell Therapy (FACT). These will be called the FACT-JACIE Standards and a working draft is already available on the JACIE website⁴. These provide further useful guidance for clinicians.

Donation

A written referral to an AA is required from the clinician responsible for the donor. The referral can be written by a stem cell transplant physician or co-ordinator, provided the name of the registered medical practitioner who has explained the procedure and the risks involved has been specified. A checklist of what is required is included at the end of this section, and an example of a referral form – Form HTA RF (DC) – from the donor clinician to the AA is included in section 7. This form may be adapted as required for local purposes.

The referral should include information under the areas detailed below. For very young donors, the discussion should be held with the person(s) accompanying the donor – in most cases, this is likely to be the person(s) with parental responsibility, who should answer the statements on the donor's behalf.

1. Confirmation that there is no other suitable donor who could act as a donor of the regenerative tissue in question. In addition, for adults who lack capacity to consent, whether it was possible to ascertain any wishes which might have been expressed while s/he still had capacity to consent.
2. Donor health status – confirmation that the donor is physically and mentally suitable for surgery and that the appropriate clinical investigations have been carried out.
3. Recipient information – to include diagnosis and relevant health history.
4. Confirmation that the donor is aware that s/he can withdraw their consent to the donation of the bone marrow / PBSC at any time before conditioning / the procedure takes place and that the risks and benefits have been explained to the donor including:
 - The procedures involved, both clinical investigations and removal of bone marrow and PBSC;
 - The long and short term risks involved and any other wider implications;
 - The possible after effects; and
 - The wider implications for the donor's dependent relatives.
5. Confirmation that the clinician responsible for the donor is satisfied that the donor's consent has been given voluntarily (i.e. not obtained by coercion, payment or the offer of any other inducement).
6. Whether the use of an independent translator has been required and, if so, form HTA IT (DC) (see section 7) is completed and signed and sent with the referral. Any translator used should have no personal connection to the donor, should have some understanding of medical matters and speak the donor's language fluently. In the case of someone with a speech or hearing disability, a translator should be used with experience in signing.

The referral form should then be sent to the AA with copies of evidence of the relationship, such as a copy of the tissue typing records for sibling donors, along with form HTA IT (DC) where a translator has been used. The referral form should also include email contact details of the clinician

⁴ <http://www.jacie.org/>

responsible for the donor and the stem cell transplant coordinator. This is to ensure that both the donor clinician and the stem cell transplant coordinator can be informed of the HTA's decision.

Checklist for the clinician responsible for the donor

1. Has the donor been assessed using a protocol based on JACIE guidance?

2. Does my written referral include the following points?

- confirmation that there is no other suitable donor and for adults who lack capacity, any wishes which might have been expressed while s/he still had capacity to consent have been taken into consideration;
- donor health status;
- recipient information;
- confirmation that the donor knows they can withdraw their consent at any time before conditioning / the procedure takes place;
- confirmation that the benefits and risks of the procedure have been explained to the donor and recipient, where appropriate⁵;
- confirmation that I am happy that there is no evidence of coercion, payment or offer of other inducement; and
- whether the use of an independent translator was required.

3. Have the following been attached to the written referral?

- completed form HTA IT (DC) where an independent translator has been used; and
- where there are concerns about mental health problems, a document detailing how they have been addressed.

4. Have I included my email address and that of the stem cell transplant co-ordinator?

⁵ In very young children, discussion with the recipient is not required

Section 5 – Duties of the Accredited Assessor

1. Before the assessment

The role of the AA is to represent the HTA in an altruistic capacity and to satisfy the requirements of the HT Act. It is not to determine medical suitability of the donor or recipient, as this is the responsibility of the responsible clinician/s. It is anticipated that in most instances of donation from children and adults lacking capacity to give informed consent, the AA will, after court approval where applicable (not applicable for Scotland) and assessment, be able to recommend approval by the HTA executive.

In order to assess any potential living donor, a written referral is first required from the clinician responsible for the donor. This referral should include the information detailed in section 4. If the use of an independent translator has been required a signed HTA IT (DC) form should be attached. If the necessary information is not included in the referral **or** the evidence of relationship is unsatisfactory, this should be sought and obtained from the clinician responsible for the donor or the stem cell transplant coordinator before the donor is seen by the AA.

The case notes of the donor and recipient should be made available if required by the AA. If the use of an independent translator is required, they should be booked to ensure they are available at the time of the interview. Any translator used should have no personal connection to the donor or the person acting on behalf of the donor, should have some understanding of medical matters, and speak the donor's language fluently. In situations where a local independent translator is not available, a facility such as 'Language Line' can be used, provided a signed declaration form is obtained. In the case of someone with a speech or hearing disability, a translator should be used with experience in signing. Any translator used should complete and sign form HTA IT (AA) (see section 7).

Where the AA is of a different cultural or ethnic background to the donor, it is permissible for a health professional colleague of that cultural / ethnic background to be present at the interview to ensure cultural / ethnic differences are considered. The health professional colleague should be independent of the donor and recipient and be present to give support to help understand cultural differences.

2. The assessment

For children and adults lacking capacity to consent, the AA's responsibility is to interview the donor, the person acting on his or her behalf (if applicable), and if necessary, the senior Consultant/Associate Specialist in charge of the donor.

It should be noted that for each donation, a separate assessment must be undertaken and the case resubmitted to the HTA for approval. This is important for repeat donation cases, since circumstances may have changed since the first assessment.

The AA should ensure that they build sufficient time into their schedule to conduct their interviews, as well as to complete their actual assessment reports. This should help to ensure that all the required criteria are met, reducing the need for the HTA to seek supplementary supporting evidence from the AA.

The interview should enable the AA to ascertain whether the following requirements have been met (for very young donors, the discussion should be held with the person(s) accompanying the donor – in most cases, this is likely to be the person(s) with parental responsibility, who should answer the statements on the donor's behalf):

- the senior Consultant/Associate Specialist has taken all reasonable steps to ensure that a suitable alternative donor is not available;

- the best interests of the donor have been properly considered (an explanation of why is required);
- where appropriate, the donor has received all the necessary information in a way that they are most able to understand;
- the senior Consultant/Associate Specialist has explained to the donor (and/or person acting on behalf of the donor), the nature of the medical procedure in question, the risks involved and any other wider implications. The report should include the information given as to the nature of the procedure and the risks involved, along with the full name of the registered medical practitioner, and their qualification, who presented this information;
- the donor (and/or person acting on behalf of the donor) understands the nature of the medical procedure in question, including the risks and the possible after effects, has the capacity to consent, and consents to the removal of bone marrow or PBSC;
- the consent was not obtained by duress or coercion or the offer of any other inducement;
- there is no evidence of an offer of reward⁶ affecting the donor's decision to consent;
- the donor (and/or person acting on behalf of the donor) understands that they are entitled to withdraw consent at any time and understands the consequences of withdrawal for the recipient;
- there were no difficulties in communicating with the donor (and/or person acting on behalf of the donor). If there were, an explanation of how those difficulties were overcome needs to be included. Any translator used should have no personal connection to the donor, should have some understanding of medical matters, and speak the language of the donor fluently. In the case of someone with a speech or hearing disability, a translator with experience in signing should be used.

The assessment procedure should be regarded as an interactive one. If the AA ascertains that there are any gaps in the information provided or doubts that all the information has been appropriately understood during the interview, they may need to refer the donor (and/or person acting on behalf of the donor) back to the referring team for further explanation before making their final assessment and recommendation to the HTA.

3. The report

Children and Adults Lacking Capacity to Consent

The report template (which can be downloaded from the HTA website) must be completed by the AA. This report allows the AA to state clearly that they are satisfied that the requirements, as listed above, have been met. Comments boxes to include qualifying remarks and/or evidence are provided where required.

If the AA is satisfied, as a representative of the HTA, that all the requirements have been met, this will need to be indicated in the report via a statement for the AA to confirm.

Once completed, the AA should send this report to the HTA who will make the final decision. The decision of the HTA executive will be communicated to the AA, the clinician responsible for the donor, and the stem cell transplant coordinator via email. A checklist of what is required of the AA is given at the end of this section.

⁶ The Acts do however allow the donor to receive reimbursement of expenses, such as travel costs and loss of earnings that are reasonably attributable to and directly result from a bone marrow or PBSC donation. Further details are available in paragraphs 54–56 of the Code of Practice on the Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells.

The report should be produced and sent to the HTA within an appropriate timeframe (that is seven to ten working days) of seeing the donor and/or the person acting on the donor's behalf. The AA is not required to keep a copy of their own notes or the report unless it is a requirement of his / her unit or they wish to do so for their own records. The HTA will keep all copies of the reports. However, until the transmission of electronic reports is possible, it is good practice for the AA to write or file the report in the patient's case notes. The AA may also wish to file the report in the recipient's case notes, but Trusts should seek their own legal advice in this matter to ensure that this is procedure is permitted.

Once approval for the donation is given by the HTA, the transplant must go ahead within six months. If not, the donor and/or the person acting on the donor's behalf will need to be seen again and a new report from an AA will be required.

4. Queries

If AA's have any concerns or queries about any application they should contact the HTA at transplants@hta.gov.uk or on 020 7211 3400.

Checklist for Accredited Assessors

Before the assessment

1. Does the written referral from the clinician responsible for the donor contain all of the required information and attachments (as per section 4)?

- Information required includes:
 - confirmation that no suitable alternative donor was available;
 - donor health status;
 - recipient information;
 - evidence of relationship;
 - confirmation that the donor, and where relevant, the other person giving consent knows they can withdraw their consent at any time before the operation takes place;
 - that the benefits and risks of the procedure have been explained to the donor and/or person acting on behalf of the donor;
 - that there is no evidence of coercion, payment or offer of other inducement; and
 - whether the use of an independent translator was required.
- Attachments that may be required include:
 - a copy of tissue typing records for sibling donors;
 - a completed HTA IT (DC) form where an independent translator has been used.

2. Is an independent translator required and if so have they been booked?

3. The date booked to see the donor and / or the person acting on the donor's behalf is within one month of receipt of referral.

4. The case notes of the donor have been requested (if required).

The Assessment

1. Ascertain the type of transplantation being considered

2. Children who lack competence to consent (in Scotland, all children) should be seen together with the person who has parental responsibility for him or her. In the rare case of an adult who lacks capacity, a member of the donor's family/carer must accompany the donor.

3. You will need to determine if the following requirements have been satisfied:

- the senior clinician has taken all reasonable steps to ensure that a suitable alternative donor is not available; and for adults who lack capacity, any wishes which might have been expressed while s/he still had capacity to consent have been taken into consideration.
- the senior clinician has explained to the donor (and/or person acting on behalf of the donor) the nature of the medical procedure, the risks involved, and any wider implications.
- The donor (and/or person acting on behalf of the donor) understands the nature of the medical procedure and the risks involved and consents to the removal of the bone marrow or PBSC.
- The consent of the donor and/or person acting on behalf of the donor has not been obtained by duress or coercion or the offer of any other inducement.
- There is no evidence of an offer of reward affecting the donor's (and/or person acting on behalf of the donor) decision to consent.
- The donor and/or person acting on behalf of the donor understand they are entitled to withdraw consent at any time and understand the consequences of withdrawal for the recipient.
- The donor-recipient relationship is as stated.

- There were no difficulties in communicating with the donor and/or person acting on behalf of the donor, and if there were, how was this overcome.

The report

1. The report template will allow the AA to state clearly that the requirements, listed above, have been met. These should be supported with qualifying remarks for each, where required, in the allocated comments boxes.
2. As a representative of the HTA are you able to recommend HTA approval for the donation to go ahead? The report to the HTA allows the AA to either:
 - Recommend approval;
 - Not recommend approval; or
 - Refrain from making a recommendation due to insufficient evidence.
3. The report should be produced and sent to the HTA via fax and post, within an appropriate timeframe of seeing the donor and/or the person acting on the donor's behalf (that is, seven to ten working days).
4. Transmission of electronic reports is currently being addressed by the HTA and this facility should be available within the first half of 2007. Please note that until the HTA has a secure online system for bone marrow/PBSC in operation, submitting AA reports via fax and post rather than email is advisable, since there is less risk of reports being intercepted or tampered with.

Section 6 – Referral, assessment and approval processes

The referral, assessment and approval process for each type of donor are summarised in this section.

6.1 Donation of Bone Marrow/PBSC from Adults Lacking Capacity

In the rare instance that there is such a case, court approval must be sought before the case can be referred to an AA (note: this step does not apply in Scotland).

Following court approval, a written referral is required from the clinician responsible for the donor to the AA. The referral should include the information and evidence of relationship as detailed in section 4 of this document. If an independent translator has been used a signed statement using form HTA IT (DC) (in section 7) should be appended.

The AA must then see the donor and the person acting on the donor's behalf⁷, and ensure that the conditions outlined in section 5 of this document are met. If an independent translator has been used a signed statement using form HTA IT (AA) (in section 7) should be appended.

The AA should then produce a written report of the interview ensuring that the conditions outlined in section 5 are included and all mandatory areas of the report have been completed. This must then be sent to the HTA executive with the AAs recommendation.

If HTA requirements are not met, then the AA will need to indicate this in the report with reasons for not recommending the donation for approval. The HTA will consider the recommendation of the AA when making its final decision.

If approval is given, the BM/PBSC transplant must go ahead within six months, otherwise a further appointment will be required with the AA for assessment and a new report from the AA will be required. If the AA is not satisfied with the new findings or needs further advice, they should consult with the HTA who can provide advice and assistance.

6.2 Donation of Bone Marrow/PBSC from Children who Lack Competence to Consent

Under the HT Act, a child is defined as a 'person who has not attained the age of 18 years'. For the purposes of the HTA assessment process, units should carefully consider all potential donors under the age of 18 (England, Wales and Northern Ireland) and whether or not they fall under the definition of 'children who lack competence to consent'. Such cases would require assessment by an AA and subsequent approval by the HTA.

Under Scots law, a child is a person who has not yet reached the age of 16 years. Under the HT (Scotland) Act, all cases involving children will need to undergo the HTA assessment procedure (see Appendix 3 – Scottish Annex for further details).

Although most AAs will be familiar with working with children, it is good clinical practice for the AA to have a certain level of understanding of working with children when conducting their assessments. Therefore, the HTA considers it best practice that assessments of children donors are carried out by an AA with training and experience in paediatrics. The AA may wish to request the input of a paediatric specialist or other AAs with paediatric expertise for such cases, as appropriate.

Where there is any dispute between persons with parental responsibility or any doubt as to the child's best interests, court approval should be sought first (this step does not apply in Scotland).

Following court approval (where necessary), a written referral is required from the clinician responsible for the donor to the AA. The referral should include the information and evidence of

⁷ This may be a member of the donor's family/carer.

relationship as detailed in section 4 of this document. If an independent translator has been used a signed statement using form HTA IT (DC) in section 7 should be appended.

The AA sees the donor and person with parental responsibility for the donor, and ensures that the conditions outlined in section 5 of this document are met.

For a child donor, the explanation and understanding of the risks is the most important condition to be met. It is also crucial to make sure that a child has consented voluntarily and has not been unduly influenced by anyone else: where older children are the donors, matters should be discussed with them first, where possible, without the person who has parental responsibility being present.

If a child indicates that they wish to withdraw consent at any point in the procedure, this consideration should be dealt with sensitively and with care, particularly if the child is distressed. Although the person with parental responsibility may want to proceed, this may not be in the best interests of the child. In such cases, the AA should consider referring such a case to a court to assist in determining the best interests of the child.

If an independent translator has been used a signed statement using form HTA IT (AA) in section 7 should be appended.

Definition of reward or coercion

Defining what constitutes reward or coercion can be difficult, since each case requires individual analysis and assessment. The paragraphs below, however, attempt to set out some guidance to assist AAs in carrying out their assessments.

The AA should make a judgement based on the individual circumstances of each case that they assess. It is important that a distinction is made between a 'normal' reward and using rewards to coerce a child into a procedure.

It is difficult to typify what constitutes an appropriate reward for a child. Children are often given rewards to compensate for an unpleasant experience, such as going into hospital or undergoing a painful procedure. This type of reward is likely to vary considerably between different families and different cultures. Parents and others may offer tangible rewards, such as a favourite food, or non tangible rewards, such as being seen as a special or helpful child, or in some cultures, spiritual recognition.

Other types of rewards, however, may be perceived by the child, and therefore in the AA's assessment, to be sufficiently desirable to influence the child's decision, thus effectively providing a means to coerce the child to donate. When trying to ascertain the effect that a given reward has had on a child's decision to donate, it is important for the AA to feel comfortable that the *child does not feel that the reward is being used to coerce them*. To this end, it could be helpful to discuss with the family beforehand whether or not the reward would still be given if the procedure did not go ahead. It is also important to ensure that the child and family understand they can withdraw consent at any time.

The complexities set out above are the kind of reward/coercion issues that the HTA would like AAs to ascertain during their interview. The HTA recognises that this can be a complex judgement to make in any individual case and that it is important that any AA who feels uncertain should seek guidance from other AAs or experienced clinicians in their place of work.

Upon completion of the interview, the AA must produce a written report of the interview ensuring that the conditions outlined in section 5 are included. This is sent to the HTA executive with a recommendation.

If the HTA requirements are not met, then the AA will need to indicate this in the report with reasons for not recommending the donation for approval. The HTA will consider the recommendation of the AA when making its final decision.

If approval is given, the transplant must go ahead within six months, otherwise a further appointment will be required with the AA for assessment and a new report from the AA will be required. If the AA is not satisfied with the new findings or needs further advice, they should consult with the HTA for assistance and advice.

Section 7 – Documentation

Contained in this section are the following forms:

- Form HTA RF (DC)
- Form HTA IT (DC)
- Form HTA IT (AA)
- Form HTA MD (DC).

Form HTA RF (DC)

HTA Model Referral Form for Clinicians – Allogenic Donation of Bone Marrow and Peripheral Blood Stem Cell Transplantation

Dear..... [AA]

**Re: Name, DOB, reference number
 Address (potential donor)
 NHS/Hospital Number**

**Name, DOB, reference number
 Address (potential recipient)
 NHS/Hospital Number**

[In lieu of inserting the above information, this space could also be left blank to insert an address]

I would be grateful if you could provide an assessment for this boy/girl whom I and my colleagues have counseled and assessed as a prospective bone marrow/PBSC *[delete as appropriate]* donor, in accordance with the HTA Codes of Practice and Guidance for transplant teams and Accredited Assessors on the Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation for the first/second time *[delete as appropriate]*.

Salient information which you may require is given below.

Section 1: Family history and relevant social information (include place of birth, nationality, UK residential status, person(s) holding parental responsibility and their name(s), number of siblings and names, any other relevant information)

Section 2: Donor information (include details of medical and psychological assessment of donor, where appropriate, and the donor's opinions on proposed donation)

Section 3: Recipient information (include details of disease, chance of cure, risks of complication, physical suitability) or see attached letter.

Section 4: Requirements under HTA Guidance

Please note that if No is answered in response to any of the statements below, further detail should be provided below. For very young donors, the discussion should be held with the person(s) accompanying the donor – in most cases, this is likely to be the person(s) with parental responsibility, who should answer the statements on the donor's behalf.

Requirement	Confirmation
The donor is the best available for the regenerative tissue in question*	Y / N
Comprehensive written and verbal information provided to both donor and recipient	Y / N
Donor and recipient understand the relevant issues and there is evidence of informed consent	Y / N
Donor understands chances of success, potential complications/risks to recipient and any wider implications	Y / N
Donor understands effects of donation and convalescence period	Y / N
There has been no coercion or duress affecting the donor's decision to consent	Y / N
Donor understands they can withdraw consent and the varying implications for recipient at each stage	Y / N
There is no evidence of reward affecting the donor's decision to consent	Y / N
The adults accompanying the donor are in agreement with one another (if applicable)	Y/N

*For adults who lack capacity to consent, please list any known wishes which might have been expressed while s/he still had the capacity to consent.

Section 5: Any other concerns to be raised

Section 6: Please list the names of the people involved in the counselling and preparation of the donor. Please include if a translator was required (and if so, please send the HTA IT (DC) with the referral).

Based on the information provided above I am satisfied/not satisfied *[delete as appropriate]* that the donor [and donor's family where applicable] is making an informed choice to donate.

Thank you for seeing this donor. Please do not hesitate to contact me if you require any further information or clarification regarding the information provided above.

Yours sincerely,

FORM HTA IT (DC)

(To be completed where the assistance of a translator has been required by the clinician responsible for the donor)

Declaration by translator

My full name is.....

and my address is.....

.....

I DECLARE THAT:

1. I(print full name)

am a translator of(specify language)

2. I was not known either to the

prospective donor(print full name)

or a person acting on the donor's behalf⁸

.....(print full name)

before being asked to translate on this matter.

3. I have translated all the discussion about the options, risks and benefits of the procedures, undertaken by the clinician responsible for the donor

.....(name of registered medical practitioner)

with a person acting on the donor's behalf and I believe that *he / she understands the purpose and content of that discussion.

.....
Signature

.....
Date

*Delete as appropriate

⁸ For adults lacking capacity this may be a member of the donor's family/carer; for children who lack competence to consent (in Scotland, all children), this will be a person with parental responsibility for the child.

FORM HTA IT (AA)

(To be completed where the assistance of a translator has been required by the Accredited Assessor)

Declaration by translator

My full name is.....

and my address is.....

.....

I DECLARE THAT:

1. I(print full name)

am a translator of(specify language)

2. I was not known either to the

prospective donor
(print full name)

or a person acting on the donor's behalf⁹

.....(print full name)

before being asked to translate on this matter.

3. I have translated the interview conducted by the Accredited Assessor

.....(name of
Accredited Assessor)

with the donor and the person acting on the donor's behalf and I believe that they both understand the purpose and content of that interview.

.....
Signature Date

⁹ For adults lacking capacity this may be a member of the donor's family/carer; for children who lack competence to consent (in Scotland, all children), this will be a person with parental responsibility for the child.

FORM HTA MD (DC)

HTA Model Declaration Form for Clinicians – Allogenic Donation of Bone Marrow and Peripheral Blood Stem Cell Transplantation

Please note that each assessment must be supported by the declaration (as below) and a copy must be attached to the patient’s notes.

I confirm that I have read and understood the HTA Code of Practice on the Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation and the Code of Practice on Consent. I have also read and understood the Draft Guidance for Transplant Teams and Accredited Assessors and have applied the principles and procedures accordingly.

Last Name.....

First Name.....

Qualification.....

Unit.....

Signature.....

Date of Assessment [dd/mm/yyyy].....

PLEASE NOTE THIS DECLARATION DOES NOT NEED TO BE SUBMITTED TO THE HTA. You should however ensure that this declaration as well as all other accompanying documents (refer to the Guidance document for further detail) are readily available should the HTA require to see them.

Section 8 – Media policy

The aim of this policy is to ensure that media interest in the HTA's remit does not have a negative effect on transplantation; that any announcements are coordinated, and none of the parties involved are caught off-guard; that the interests of all parties involved in the transplantation processes are taken into account and that any issues decision making are discussed. It is particularly important that a responsible approach to announcements is taken so as not to give false hope, particularly to patients and families in the media.

Media involvement

BMT teams should be aware when advising families, that the HTA does not consider it favourable for the media to be involved in the procedure of approving donations, since this could be interpreted as undue duress or coercion. Trusts are advised not to publicise the transplant until the actual approval for the donation has gone ahead. The HTA advises as best practice that AAs state in their reports, if the media has had any involvement at any stage of the assessment procedure. If the AA finds that there is evidence of undue duress or coercion based on media involvement, they can recommend that the donation does not go ahead. If there is any hesitancy on the side of the AA, they should recommend that they are unsure as to whether the donation should go ahead, and then further discuss the issue with the HTA, seeking advice on how to proceed.

Media announcements by HTA or Hospital Trusts (in Scotland, Acute Operating Divisions)

Any decision made by the HTA on living donor transplantation should be announced by the HTA, and not any other party. Notice should be given on all sides to ensure that any media announcement is coordinated. HTA should have the first opportunity to comment on their approval process and ethical issues. The BSBMT has a role in promoting transplantation and it is recommended they are also kept informed. Any sensitive paediatric issues should also be raised with the Chair of the UK Children's Cancer Study Group (UKCCSG) BMT group, as well as the HTA.

Media contact with Bone Marrow transplant units or AAs or Hospital Trusts

The HT Act requires us to inform the public about activities within our remit.

AAs and stem cell transplant teams may be contacted by media about the HTA's business, which covers a number of areas, including transplantation. The policy which these parties are requested to comply with is as follows:

The HTA communications department are informed and provided with:

- the name of the journalist;
- contact details (phone and email);
- the request;
- what the issue is and their view on it / line to take;
- the deadline; and
- the name and contact details for a representative of the Hospital Trust's communications department.

In a Hospital Trust, it is likely to be policy that media interest is referred to with the Trust's communications department. It is requested that this communications policy, as well as contact details for the HTA communications department are provided to them. It may also be helpful if the President of the BSBMT media office and the Chair of the UKCCSG BMT group are informed.

Media can be pointed to any information that is in the public domain, for example the HTA website.

The following are key issues in relation to transplantation that the media may be interested in over the coming months:

- The regulation of donation of bone marrow and PBSC from adults lacking capacity and non-competent children.
- Training of AAs.
- Accreditation process.

HTA key messages – general, and in relation to transplantation

- The HTA's aim is to put in place an effective regulatory system for the removal, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence.
- We will not hold up potentially life-saving activities like transplantation, or medical and scientific research.

Contact details for HTA communications department:

Dr Shaun Griffin, Head of Communications

Email shaun.griffin@hta.gov.uk

Tel 020 7211 3423

Mob 07814 522 581

Daisy Thomas, Communications Manager

Email daisy.thomas@hta.gov.uk

Tel 020 7211 3417

Stuart Giblin Communications Officer

Email stuart.giblin@hta.gov.uk

Tel 020 7211 3416

Appendix 1 – Extract from England, Wales and Northern Ireland Regulations

PART 3: TRANSPLANTS

Meaning of transplantable material for the purposes of Section 34 of the HT 2004 Act

9. For the purposes of section 34 of the Act (information about transplant operations) "transplantable material" means—

(a) the whole or part of any of the following organs if it is to be used for the same purpose as the entire organ in the human body—

(i) kidney,

(ii) heart,

(iii) lung or a lung lobe,

(iv) pancreas,

(v) liver,

(vi) bowel,

(vii) larynx;

(b) face, or

(c) limb.

Meaning of transplantable material for the purposes of Section 33 of the HT 2004 Act

10. —(1) Subject to paragraphs (2) and (3), for the purposes of section 33 of the Act (restriction on transplants involving a live donor), "transplantable material" means—

(a) an organ, or part of an organ if it is to be used for the same purpose as the entire organ in the human body,

(b) bone marrow, and

(c) peripheral blood stem cells,

where that material is removed from the body of a living person with the intention that it be transplanted into another person.

(2) The material referred to in paragraph (1)(a) is not transplantable material for the purposes of section 33 of the Act in a case where the primary purpose of removal of the material is the medical treatment of the person from whose body the material is removed.

(3) The material referred to in paragraph (1)(b) and (c) is transplantable material for the purposes of section 33 of the Act only in a case where the person from whose body the material is removed is—

(a) an adult who lacks the capacity, or

(b) a child who is not competent,

to consent to removal of the transplantable material.

Cases in which restriction on transplants involving a live donor is disapplied

11. —(1) Section 33(1) and (2) of the Act (offences relating to transplants involving a live donor) shall not apply in any case involving transplantable material from the body of a living person ("the donor") if the requirements of paragraphs (2) to (6) are met.

(2) A registered medical practitioner who has clinical responsibility for the donor must have caused the matter to be referred to the Authority.

(3) The Authority must be satisfied that—

(a) no reward has been or is to be given in contravention of section 32 of the Act (prohibition of commercial dealings in human material for transplantation), and

(b) when the transplantable material is removed—

(i) consent for its removal for the purpose of transplantation has been given,
or

(ii) its removal for that purpose is otherwise lawful.

(4) The Authority must take the report referred to in paragraph (6) into account in making its decision under paragraph (3).

(5) The Authority shall give notice of its decision under paragraph (3) to—

(a) the donor of the transplantable material or any person acting on his behalf,

(b) the person to whom it is proposed to transplant the transplantable material ("the recipient") or any person acting on his behalf, and

(c) the registered medical practitioner who caused the matter to be referred to the Authority under paragraph (2).

(6) Subject to paragraph (7), one or more qualified persons must have conducted separate interviews with each of the following—

(a) the donor,

(b) if different from the donor, the person giving consent, and

(c) the recipient,

and reported to the Authority on the matters specified in paragraphs (8) and (9).

(7) Paragraph (6) does not apply in any case where the removal of the transplantable material for the purpose of transplantation is authorised by an order made in any legal proceedings before a court.

(8) The matters that must be covered in the report of each interview under paragraph (6) are—

- (a) any evidence of duress or coercion affecting the decision to give consent,
- (b) any evidence of an offer of a reward, and
- (c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

(9) The following matters must be covered in the report of the interview with the donor and, where relevant, the other person giving consent—

(a) the information given to the person interviewed as to the nature of the medical procedure for, and the risk involved in, the removal of the transplantable material,

(b) the full name of the person who gave that information and his qualification to give it, and

(c) the capacity of the person interviewed to understand—

(i) the nature of the medical procedure and the risk involved, and

(ii) that the consent may be withdrawn at any time before the removal of the transplantable material.

(10) A person shall be taken to be qualified to conduct an interview under paragraph (6) if—

(a) he appears to the Authority to be suitably qualified to conduct the interview,

(b) he does not have any connection with any of the persons to be interviewed, or with a person who stands in a qualifying relationship to any of those persons, which the Authority considers to be of a kind that might raise doubts about his ability to act impartially, and

(c) in the case of an interview with the donor or other person giving consent, he is not the person who gave the information referred to in paragraph (9)(a).

Decisions of the Authority: procedure for certain cases

12. —(1) In any case to which paragraph (2), (3) or (4) applies, the Authority's decision as to the matters specified in regulation 11(3) shall be made by a panel of no fewer than 3 members of the Authority.

(2) A case falls within this paragraph if—

(a) the donor of the transplantable material is a child, and

(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(3) A case falls within this paragraph if—

(a) the donor of the transplantable material is an adult who lacks capacity to consent to removal of the material, and

(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(4) A case falls within this paragraph if—

(a) the donor of the transplantable material is an adult who has capacity to consent to removal of the material, and

(b) the case involves—

(i) paired donations,

(ii) pooled donations, or

(iii) a non-directed altruistic donation.

(5) In this regulation—

"non-directed altruistic donation" means the removal (in circumstances not amounting to a paired or pooled donation) of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him;

"paired donations" means an arrangement under which—

(a) transplantable material is removed from a donor ("D") for transplant to a person who is not genetically related or known to D, and

(b) transplantable material is removed from another person for transplant to a person who is genetically related or known to D; and

"pooled donations" means a series of paired donations of transplantable material, each of which is linked to another in the same series (for example, transplantable material from D is transplanted to the wife of another person ("E"), transplantable material from E is transplanted to the partner of a third person ("F") and transplantable material from F is transplanted to D's son).

Right to reconsideration of Authority's decision

13. —(1) The Authority may reconsider any decision made by it under regulation 11(3) if it is satisfied that—

(a) any information given for the purpose of the decision was in any material respect false or misleading, or

(b) there has been any material change of circumstances since the decision was made.

(2) A specified person may in any case require the Authority to reconsider any decision made by it under regulation 11(3).

(3) "Specified persons", in relation to such a decision, are—

(a) the donor of the transplantable material or any person acting on his behalf,

(b) the recipient of the material or any person acting on his behalf, and

(c) the registered medical practitioner who caused the matter to be referred to the Authority under regulation 11(2).

(4) The right under paragraph (2) is exercisable by giving to the Authority, in such manner as it may direct, notice of exercise of the right.

(5) A notice under paragraph (4) shall contain or be accompanied by such other information as the Authority may reasonably require.

(6) On receipt of the information required by paragraph (5), the Authority shall provide to the person requiring the reconsideration—

(a) a copy of each report made under regulation 11(6) of the interviews that were conducted in the case, and

(b) a statement of the Authority's reasons for its decision.

(7) Paragraphs (1) to (6) do not apply to a decision made by the Authority on reconsideration in pursuance of a notice under this regulation.

Procedure on reconsideration

14.—(1) Reconsideration shall be by way of fresh decision made at a meeting of the Authority.

(2) The meeting shall take place as soon as reasonably practicable after the provision of the reports and statement required by regulation 13(6), having regard to the need to allow time for the information contained in that material to be taken into account.

(3) Where a member of the Authority has taken part in the making of a decision subject to reconsideration (whether under regulation 12 or otherwise), he is disqualified from participating in the Authority's reconsideration of it.

(4) On reconsideration under regulation 13(2)—

(a) the person ("A") by whom the reconsideration is required under regulation 13(2) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard at the meeting of the Authority at which the decision is reconsidered, and

(b) the members of the Authority in attendance at the meeting at which the decision is reconsidered shall consider any such written representations and comments.

(5) The Authority shall give a notice of its decision to A.

(6) If on reconsideration the Authority upholds the previous decision, the notice under paragraph (5) shall include a statement of the reasons for the Authority's decision.

(7) "Reconsideration" means reconsideration in pursuance of a notice under regulation 13.

Appendix 2 – Confidentiality

The information provided in the AA reports is clearly of a sensitive and confidential nature.

The Data Protection (DP) Act¹⁰ aims to secure the right of individuals to privacy by protecting information that is held about them. Any public authority, which includes the HTA, that handles personal data, must comply with the data protection principles which control how such data is processed.

These principles state that data must be:

- 1) Fairly and lawfully processed
- 2) Processed for limited purposes
- 3) Adequate, relevant and not excessive
- 4) Accurate
- 5) Not kept for longer than is necessary
- 6) Processed in line with your rights
- 7) Secure
- 8) Not transferred to countries without adequate protection.

Since in the AA report, there would be other information other than just the personal information, in the case that a person who is identified in the report requested information about him/herself, the HTA could redact the information which did not apply and send the person that data which applied to them only.

If a member of the public makes a request for information about another living individual, such as requesting details related to the donor in the AA report, this would be handled under the Freedom of Information (FOI) Act¹¹. Data protection considerations will still apply and the HTA will not have to provide the information if the disclosure would breach the data protection principles (as stated above). In the case of the AA report, data principles 2 and 7 would apply. To substantiate this, under S41 of the FOI Act, there is an exemption relating to Information provided in confidence. The HTA could therefore apply this exemption as well as quote data protection considerations, if there was a request from a member of the public for access to an AA report.

¹⁰ <http://www.opsi.gov.uk/ACTS/acts1998/19980029.htm>

¹¹ <http://www.opsi.gov.uk/acts/acts2000/20000036.htm>

Appendix 3 – Scottish Annex: requirements relating to living donation

Introduction

The Scottish Ministers and the Human Tissue Authority (HTA) have agreed that the HTA will act on the Scottish Ministers' behalf in relation to cases of living donation involving Scotland, in order to promote consistency of approach across the UK. The general arrangements set out in the HTA's Codes of Practice on the Donation of organs, tissues and cells for transplantation and the Donation of allogeneic bone marrow and peripheral blood stem cells (PBSC) for transplantation therefore apply to Scottish cases. There are, however, some important differences, relating mainly to the types of Scottish cases which can be considered by the HTA. These restrictions, which stem from the extension to the living donation arrangements of the principles of Scots law relating to children and adults with incapacity, are described in more detail in this Annex.

The Scottish Legal Framework

The legal framework for living donation and transplantation is set out in Section 17 of the [Human Tissue \(Scotland\) Act 2006](#) (herewith referred to as the (HT) Scotland Act), and in general applies to a part of the body which can be removed from a living person for the purpose of transplantation. The provisions of Section 17 are supplemented by those in the [Human Organ and Tissue Live Transplants \(Scotland\) Regulations 2006](#) (herewith referred to as the Scottish Live Transplants Regulations). Although the (HT) Scotland Act and these Regulations refer to 'the Scottish Ministers', this has been done for technical legal reasons and in practical terms should be understood as meaning the HTA.

There are 3 broad categories of potential donors: adults who have the capacity to make their own decisions; adults who lack that capacity; and children. There are restrictions on each in terms of living donation, and the Scottish Live Transplants Regulations set out the circumstances in which those restrictions can be lifted by the HTA. The common requirements are that the HTA has to be satisfied that:

- no reward has been or is to be given in contravention of section 20 of the (HT) Scotland Act, which prohibits commercial dealings in parts of a human body for transplantation;
- there is no evidence of duress or coercion affecting the donor's decision; and
- the relevant requirements of the Scottish Live Transplants Regulations under the (HT) Scotland Act have been met.

For adults with capacity, the position is as described in these Codes, bearing in mind that someone becomes an adult in Scotland when they reach the age of 16. The Scottish Live Transplants Regulations do not apply to the donation of regenerative tissue by adults with capacity, but such cases involving an adult in Scotland are subject to the administrative arrangements set out in the Code of Practice on the donation of allogeneic bone marrow and PBSC.

For adults with incapacity (AWI), the (HT) Scotland Act applies the principles embodied in the [Adults with Incapacity \(Scotland\) Act 2000](#). The only types of donation open to AWI are (1) regenerative tissue, and (2) an organ or part of an organ in the circumstances where it has to be removed from the AWI as part of a domino organ transplant operation. In relation to the donation of regenerative tissue, the Scottish Live Transplants Regulations include additional protections for the AWI based on the 2000 Act. A form has to be completed certifying that the adult does not have the capacity to understand what is involved in the donation of regenerative tissue. The form is prescribed in the [Schedule to the Adults with Incapacity \(Removal of Regenerative Tissue for Transplantation\) \(Form of Certificate\) \(Scotland\) \(No. 2\) Regulations 2006](#). The Scottish Live Transplants Regulations also stipulate that there is no other adult who could act as a donor, that removal of the regenerative tissue involves at most a minimal foreseeable risk and no more than minimal discomfort to the donor, and that the AWI has not indicated unwillingness to be a donor. With this last point in mind, the Scottish Live Transplants Regulations provide that the adult's nearest relative, principal carer or proxy should be included in the interview process wherever possible, so that account can be taken of any views the adult might have expressed before losing capacity.

The position regarding children is broadly similar to that for AWI. In Scots law, a child is a person who has not yet reached the age of 16. The provisions of the (HT) Scotland Act and the associated Regulations apply to all children in Scotland. The only forms of donation open to them are an organ or part of an organ which has to be removed as part of a domino organ transplant operation, or regenerative tissue. It is not possible for children to take these decisions themselves, even though they may be thought capable of understanding the issues involved. In those cases, their views can be taken into account, but the decisions must be taken by the HTA. In reaching its decision, the HTA can also take account of the views of those with parental rights and responsibilities for the child, though a local authority in that position is excluded from the process.

Because the Scottish Live Transplants Regulations are couched in terms of 'the Scottish Ministers', it has not been possible within them to make the distinction which exists in the equivalent English Regulations¹² between decisions which can be taken by the HTA itself or those decisions which have to be taken by a panel of no fewer than 3 members of the HTA. In practical terms, however, that distinction will be applied to Scottish cases in the same way as it is to equivalent cases in the rest of the UK.

The Scottish Live Transplants Regulations provide for reconsideration of decisions by the HTA, but contain an additional provision allowing for anyone who is involved in a case and is aggrieved by the HTA's decision in that case to appeal to the Court of Session.

¹² Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.