

Donor Consent Guidelines

Purpose

To ensure that all clinical staff comply with legislation and policies for obtaining consent for donation and clinical investigations including serological testing.

Scope

This document refers solely to allogeneic donors, donating bone marrow ,peripheral blood stem cells or lymphocytes

Responsibilities

Clinical Director

Responsible for ensuring that, Specialist Registrars, Consultants and Clinical Nurse Specialists are trained in the consent process.

Responsible for ensuring that best practise is maintained and reviewed.

Nurse Managers

Responsible for ensuring that all nursing staff are aware of their responsibilities with regard to ensuring verbal consent and reviewing written consent.

Those undertaking consent

Responsible for ensuring they attend updates and training as provided.

Responsible for ensuring they are familiar with and use the principles of:

When to consent	Who is responsible for the consent process
Provision of information	Obtaining valid consent
Capacity to consent	Parental consent
Consenting children	Documentation required
HTA documentation	

Documentation

OUH Consent Policy (2007)	Human Tissue Act (2004)
Human Tissue Authority. Directions given under the Human Tissue Act 2004: 001/2006.	Human Tissue (Quality and Safety for Human Application) Regulations 2007. Human Tissue 2007 No.1523. Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, April 2018.
Human Tissue Authority. Directions given under the Human Tissue Act 2004: 002/2007	Human Tissue Authority (2009) Code of practice 1. Consent. Code of practice 6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.
OUH Consent Forms	NHSBT TAS Consent forms & guidance
MRHA Good Clinical Practice	GMC (2008) Consent: patients and doctors making decisions.
Guidance on professional standards and	

ethics for doctors Decision making and consent(GMC updated guideline 9.11.2020)	
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Department of Clinical Haematology Accredited Assessors (HTA):

Dr Andy Peniket, Consultant Haematologist

Training

1. All appropriate staff undertake departmental consent training, which includes current OUH policy, HTA Codes of practice and other appropriate legislation and guidance on induction. Training updates are biennial.
2. Specialist Registrars during their training and clinical Fellows are GCP trained.
3. Consultants are GCP trained.
4. GCP updates are undertaken biennially.
5. Ward nursing staff review the consent process training biennially and on induction.
6. Consent training is part of staff CPD.

Process

1. Consent to testing and donation should only be taken by an appropriately trained Doctor or Clinical Nurse Specialist.
2. All communication regarding consent should be undertaken in a private, confidential, disturbance free environment and in a manner and using terms that are easily understood.
3. Donors should be offered the opportunity prior to the meeting to bring a support person with them.
4. The donor must be reliably identified.
5. The initial meeting/conversation will cover all aspects of the donation, with written information provided as appropriate.
6. Information regarding donation must cover at least the purpose and nature of the donation, its consequence and risks, any analytical tests if they are performed, the recording and protection of donor data and medical confidentiality, therapeutic purpose and potential benefits of donation and information on applicable safeguards to protect the prospective donor.
7. The donor must be informed that he/she has the right to receive confirmed results of the analytical tests in a manner and using terms that are easily understood by the donor.
8. The donor must be informed of the necessity for obtaining his/her consent in order that the procurement of the bone marrow or peripheral blood stem cells is carried out.
9. An opportunity to have time to consider the information will be offered and an appropriate time to re-convene negotiated as appropriate.
10. The donor will be given contact details of the Clinical Nurse Specialist to contact with any further questions or support needs.
11. Written consent must be obtained following the OUH Trust policy.
12. For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.

13. Immediately prior to harvest, consent must be reaffirmed and this documented.

Documentation of consent

1. The following should be clearly and legibly documented in the donor notes:
 - a) date, time and name of person taking consent
 - b) what is being consented to
 - c) names of those present during the discussion
 - d) the consent process as outlined above
 - e) information giving, including risks and benefits
 - f) provision of written literature and version number
 - g) pertinent patient questions
 - h) any difficulties with communication and how these were overcome
 - i) a statement by the donor that they have received sufficient information to give informed consent
 - j) the consent decision
 - k) any agreed time frames
2. Completed OUH and/or NHSBT consent forms are filed, at the time of consenting, in the donor notes.
3. For donors, a signed declaration by the clinician stating they have read and applied the HTA's Code of Practice should be filed in the donor's medical notes before a harvest procedure. A copy of this form is available on the TSSG website or www.hta.gov.uk.

Provision for patients whose first language is not English

1. Translation and interpretation services are available via the OUH Patient Advice and Liaison Service.
2. As a department, consent and the imparting of information related to consent, is not undertaken using donor family members.

Audit

1. Audit of the consent process is undertaken via the departments audit programme.
2. Independent audit is undertaken biennially.
3. Staff practice is peer reviewed biennially. This is undertaken by peer supervision, using the guidelines above, of 2-3 consenting sessions with constructive feedback.

Author

Sandy Hayes, September 2010.

Review

Name	Revision	Date	Version	Review date
Sandy Hayes, Quality manager.	ORH policy change, delegated consent procedure	July 2011	1.1	July 2013
Sandy Hayes, Quality	OUH name	May 2012	1.2	July 2013

Department of Clinical Haematology
Oxford BMT Programme

manager	change			
Dr Tim Littlewood, HTA DI.	No changes	Sept2013	1.3	Sept 2015
Sandy Hayes, Quality Manager, HTA Person designate	Update, HTA guidance	Nov2015	2.0	Nov2017
Sandy Hayes, Quality manager	Update	April 2016	2.1	April 2018
Rachel Pawson, NHSBT Consultant	Minor Amendments	March 2021	2.2	March 2023
Nadeera Jayasekara, Registrar	Amendments to scope and guidance	June 2023	2.3	June 2025