Patient Consent Guidelines

Principle
To ensure that all clinical staff comply with legislation and policies for obtaining patient consent for autologous harvest of bone marrow or peripheral blood stem cells, clinical investigations, clinical treatments, and biomedical research.

Scope
This guideline encompasses staff employed by the Department of Clinical Haematology.

Responsibilities
Clinical Director
Responsible for ensuring that, Specialist Registrars, Consultants and Nurse Practitioners 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.
Undertake delegated consent training as appropriate.
Responsible for ensuring they are familiar with and use the principles of:

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Delegated consent

Documentation

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<tr>
<td>OUH Consent Forms</td>
<td>NHSBT STS/SCI Consent forms and guidance</td>
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</table>
Human Tissue Authority (HTA) Accredited Assessor’s:
Dr Andy Peniket, Consultant Haematologist
Denise Wareham, Advanced Nurse Practitioner, BMT Co-ordinator.

Training
1. All appropriate staff undertake departmental consent training, which includes current OUH policy, HTA Code of practice and other appropriate legislation and guidance on induction. Training updates are biennial.
2. Specialist Registrar’s undertake Delegated Consent Training at various stages throughout their training (H.42 Delegated consent procedure)
3. Specialist Registrar’s during their training, are GCP trained.
4. Consultants are GCP trained.
5. GCP updates are undertaken biennially
6. Ward nursing staff review the consent process training biennially and on induction.
7. Consent training is part of staff CPD.

Process
1. Consent for autologous harvest of bone marrow or peripheral blood stem cells, clinical investigations, clinical treatments, and biomedical research should only be taken by an appropriately trained Doctor or Nurse practitioner.
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. Patients should be offered the opportunity prior to the meeting to bring a support person with them.
4. The patient must be reliably identified.
5. The initial meeting will cover all aspects of the treatment, with written information provided as appropriate.
6. Information regarding treatment must cover at least the purpose and nature of the treatment, its consequence and risks, any analytical tests if they are performed, the recording and protection of patient data and medical confidentiality, therapeutic purpose and potential benefits of treatment and information on applicable safeguards to protect the patient.
7. The patient must be informed that he/she has the right to receive confirmed results of the analytical tests and in a manner and using terms that are easily understood by the patient.
8. The patient 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 or for treatment to take place.
9. An opportunity to have time to consider the information will be offered and an appropriate time to re-convene negotiated as appropriate.
10. Patient will be given contact details of the Nurse practitioner 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 procedure, treatment or harvest, consent must be reaffirmed and this documented.
Documentation of consent
1. The following should be clearly and legibly documented in the patient notes:
   a) date, time and name of person taking consent
   b) what is being consented to
   c) the consent process as outlined above
   d) information giving, including risks and benefits
   e) provision of written literature and version number
   f) any difficulties with communication and how these were overcome
   g) a statement by the patient that they have received sufficient information to give informed consent
   h) the consent decision
   i) any agreed time frames
2. Completed OUH and/or NHSBT consent forms are to be filed chronologically, at the time of consenting by the consenter, in the patient notes.

Provision for patients whose first language is not English
1. Translation and interpretation services are available via the OUH approved provider
2. As a department, consent and the imparting of information related to consent, is not undertaken using patient family members.

Audit
1. Audit of the consent process is undertaken via the OUH audit programme.
2. Department audit is undertaken biennially.
3. .

Author
Sandy Hayes, September 2010.

Review

<table>
<thead>
<tr>
<th>Name</th>
<th>Revision</th>
<th>Date</th>
<th>Version</th>
<th>Review date</th>
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<tr>
<td>Sandy Hayes, Quality manager</td>
<td>ORH policy change, delegated consent procedure</td>
<td>July 2011</td>
<td>1.1</td>
<td>July 2013</td>
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<tr>
<td>Sandy Hayes, Quality manager</td>
<td>OUH name change</td>
<td>May 2012</td>
<td>1.2</td>
<td>July 2013</td>
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<tr>
<td>Dr Tim Littlewood</td>
<td>No changes</td>
<td>Sept 2013</td>
<td>1.3</td>
<td>Sept 2015</td>
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<tr>
<td>Sandy Hayes, Quality manager</td>
<td>Update, HTA guidance</td>
<td>Nov 2015</td>
<td>2.0</td>
<td>Nov 2017</td>
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