Salisbury NHS
NHS Foundation Trust

Patient agreement consent form for Autologous Stem Cell Transplantation

Designed in compliance with the Department of Health Consent Form 1

Patient details (or pre-printed label)	
Patients NHS Number or Hospital Number	
Patients Surname / Family Name	
Patients First Name(s)	
Date of Birth	
Sex	
Responsible Healthcare Professional	
Job Title	
Special Requirements e.g. other language or other communication method	

Informed consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue Regulations 2007 and the HTA's Codes of Practice.

Tissue samples

Tissues (including blood) may be removed during your procedure for diagnostic examination by a pathologist (a specialist doctor who looks at tissue from patients). Tissue samples needed for diagnosis are stored by the laboratory for several years. The stored tissue may be anonymously used for laboratory quality control, audit and education. These are essential activities for maintaining high quality diagnostic pathology services. Any remaining excess tissue removed is incinerated.

The specimen may be digitally photographed and the images temporarily stored in the laboratory as part of the diagnostic process. Other completely anonymised images may also be used for quality assurance, audit and education purposes.

Occasionally stored tissues and photographs might be used for research projects. Any such research will have been approved by a research ethics committee (REC). Usually any pathology specimens used for research are made completely anonymous, so that individual patients cannot be identified in any way. If this is not possible, the REC will require the researcher to contact you and ask permission to use your stored tissue or photographs. You would then be free to decide whether or not to allow the use of the material. Your decision would not in any way affect your medical care.

Patient identifier/label

Notes Copy

Name of Proposed Procedure (include a brief explanation if medical term not clear)
Autologous Stem Cell Transplant Autologous transplantation: conditioning with (specify):

Statement of health professional (To be filled in by health professional with appropriate knowledge of the proposed procedure, as specified in the consent policy).

Human Tissue Authority Statement

I have read and applied the Human Tissue Authority's codes of practice on consent and confirm that the patient has received and understood sufficient information to give informed consent

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits:

❑ Curative – to give you the best possible chance of being cured.

❑ Palliative – the aim is not to cure, but to control the disease. The aim is to keep you as well as possible for as long as possible.

Significant, unavoidable or frequently occurring risks	tick
Transplant mortality	❑
Bone marrow suppression (including anaemia, infection, bleeding)	❑
Nausea & vomiting	❑
Mucositis	❑
Organ toxicity	❑
Late effects (including infertility and secondary malignancy)	❑
Other including those specific to the patient:	❑

Document any consent variations here

I have discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

❑ The following leaflet / tape has been provided:

I have discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient. I have checked that the patient has no outstanding queries and all their questions have been answered to their satisfaction. I have given them the information sheet(s) as detailed above.

Signed:	Date:
Name (PRINT)	Job Title:

Contact Details (if patient wishes to discuss options later) _____

Statement of interpreter (where appropriate). I have interpreted the information above to the patient to the best of my ability and in a way I believe s/he can understand.

Signature of Interpreter _____Name (print) _____ Date _____

Copy accepted by patient: Yes / No (please ring)
When consent form completed, please make a copy and file in the patient's health care record

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to the one described on this form will only be carried out if it is necessary to save my life or prevent serious harm to my health.

I understand that data about me will be held electronically and may be passed between the European Bone Marrow Transplant Registry (The Netherlands) and the International Bone Marrow Transplant Registry (USA) to facilitate research and care.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

_____

_____

Patient's signature	Name (PRINT)	Date:

A witness should sign below if the patient is unable to sign, but has indicated his or her consent. Female patients between the age of 16 and 50 years please read the following statements:

- ❑ I confirm that I am not pregnant
- ❑ I understand that I need to avoid becoming pregnant during the course of my treatment
- ❑ If I think I might be pregnant, I will inform the staff treating me

Patient's signature	Name (PRINT)	Date:

A witness should sign below if the patient is unable to sign, but has indicated his or her consent.

Signature	Name (PRINT)	Date:

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed:	Date
Name (PRINT)	Job Title

Important notes: (tick if applicable)

- ❑ See also advanced directive/living will (e.g. Jehovah's Witness form).
- ❑ Patient has withdrawn consent (ask patient to sign/date here) _____

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to the one described on this form will only be carried out if it is necessary to save my life or prevent serious harm to my health.

I understand that data about me will be held electronically and may be passed between the European Bone Marrow Transplant Registry (The Netherlands) and the International Bone Marrow Transplant Registry (USA) to facilitate research and care.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

_____

_____

Patient's signature	Name (PRINT)	Date:

A witness should sign below if the patient is unable to sign, but has indicated his or her consent. Female patients between the age of 16 and 50 years please read the following statements:

- ❑ I confirm that I am not pregnant
- ❑ I understand that I need to avoid becoming pregnant during the course of my treatment
- ❑ If I think I might be pregnant, I will inform the staff treating me

Patient's signature	Name (PRINT)	Date:

A witness should sign below if the patient is unable to sign, but has indicated his or her consent.

Signature	Name (PRINT)	Date:

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed:	Date
Name (PRINT)	Job Title

Important notes: (tick if applicable)

- ❑ See also advanced directive/living will (e.g. Jehovah's Witness form).
- ❑ Patient has withdrawn consent (ask patient to sign/date here) _____