Salisbury NHS
NHS Foundation Trust

Haematology/Oncology Department Patient agreement to Systemic Therapy

Lenalidomide (Revlimid) Cyclophosphamide and Dexamethasone (RCD)

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 may be removed during your procedure for diagnostic examination by a histopathologist (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

Name of proposed procedure or course of treatment		
Systemic therapy	☐	Cytotoxic chemotherapy (Lenalidomide, Cyclophosphamide + Dexamethasone (RCD))
	☐	Immunotherapy
	☐	Both
	☐	Lumbar puncture with intrathecal chemotherapy

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

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

The intended benefits:

☐ **Palliative** - the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival.

General risks of the therapy

Damage to unborn babies (see next page), lowered resistance to infection, bruising or bleeding, blood clots in veins and in the lungs, muscle cramps or weakness, diarrhoea, constipation, nausea (feeling sick), vomiting (being sick), tiredness, difficulty sleeping, changes in body weight.

❑ The following leaflet / tape has been provided: _____ Version: ___

❑ The Pembroke Unit Alert card has been given to the patient.

❑ The Hand-held diary has been given to the patient (if appropriate).

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)
If yes, please copy all pages and give to the patient

Patient identifier/label

Statement of patient

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 or course of treatment 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 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 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. _____

_____

Lenalidomide (Revlimid) may cause damage to unborn babies

1. Female patients who are able to become pregnant please read the following statements:

- If you are pregnant, if you think you may be pregnant or are planning to become pregnant you must **not** take Lenalidomide.
- Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant and should therefore agree to follow precautions below:

☐ I agree that I will use adequate contraception starting 4 weeks before Lenalidomide treatment, during Lenalidomide treatment and for 4 weeks after stopping Lenalidomide treatment.

or

☐ I agree that I will not engage in sexual activity with a male partner starting 4 weeks before Lenalidomide treatment, during Lenalidomide treatment and for 4 weeks after stopping Lenalidomide treatment. I understand that I will be asked to confirm this every 4 weeks.

and

☐ I understand that I must have a pregnancy test to make sure that I am not pregnant before starting Lenalidomide and every 4 weeks during treatment.

2. Male patients (including those who have had a vasectomy) please read the following statements:

☐ I agree to use a condom every time I have sexual contact with a woman who is able to become pregnant and who does not use effective contraception throughout my Lenalidomide treatment, during any breaks in treatment and for 1 week after stopping treatment.

☐ I understand that I must not donate sperm during treatment or for 1 week after treatment finishes.

Please turn over and sign where indicated

Patient identifier/label

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. Young people/children may also like a parent to sign here.

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 has agreed to participation in clinical trial (see separate consent form).