PATIENT AGREEMENT TO SYSTEMIC ANTI-CANCER THERAPY: Rituximab

PATIENT DETAILS

PATIENT'S SURNAME/FAMILY NAME: _____

PATIENT'S FIRST NAME(S): _____

DATE OF BIRTH: _____

NHS NUMBER: _____
(or other identifier)

☐ MALE ☐ FEMALE

SPECIAL REQUIREMENTS:
(e.g. other language/other communication method)

HOSPITAL NAME/STAMP: _____

RESPONSIBLE HEALTH PROFESSIONAL:

Name: _____

Job title: _____

NAME OF PROPOSED COURSE OF TREATMENT (include brief explanation if medical term not clear)

☐ Rituximab for the treatment of cutaneous lymphoma.

☐ Given intravenously on day 1, every 7 days for up to 4 weeks.

WHERE THE TREATMENT WILL BE GIVEN:

☐ outpatient ☐ day unit/case ☐ inpatient ☐ other: _____

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust's consent policy)

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

☑ all relevant boxes

THE INTENDED BENEFITS

☐ **CURATIVE** – to give you the best possible chance of being cured.

☐ **DISEASE CONTROL/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.

☐ **ADJUVANT** – therapy given after surgery to reduce the risk of the cancer coming back.

☐ **NEO-ADJUVANT** – therapy given before surgery/radiotherapy to shrink the cancer, allow radical treatment and reduce the risk of the cancer coming back.

STATEMENT OF HEALTH PROFESSIONAL (continued)

Patient identifier/label

SIGNIFICANT, UNAVOIDABLE OR FREQUENTLY OCCURRING RISKS

COMMON SIDE EFFECTS:

More than 10 in every 100 (>10%) people have one or more of the side effects listed:

- ☐ Thinning of hair or hair loss, bruising or bleeding, tiredness and feeling weak (fatigue).
- ☐ An increased risk of getting an infection from a drop in white blood cells - it is harder to fight infections and you can become very ill.

  If you have a severe infection this can be life threatening. Contact you doctor or hospital straight away if:

  • your temperature goes over 37.5°C (99.5°F) or over 38°C (100.4°F), depending on the advice given by your chemotherapy team

  • you suddenly feel unwell (even with a normal temperature)
- ☐ Infusion-related reactions causing flu-like symptoms (high temperature, chills, muscle aches, dizziness, headaches), allergic reactions (rash, itching, feeling of swelling or irritation in the tongue, throat and nasal passages, breathlessness), irregular heart rate, blood pressure changes and hot flushes. You may notice these while the drug is given or within 1-3 hours. Symptoms are usually most noticeable with the first dose, and less noticeable subsequently.

OCCASIONAL SIDE EFFECTS:

Between 1 and 10 in every 100 (1-10%) people have one or more of these effects:

- ☐ Anaemia (low number of red blood cells), fluid retention (you may notice you gain weight and/or your ankles and legs swell), high blood sugar levels, numbness or tingling of the skin, hands and feet, increased sweating, anxiety, difficulty sleeping, eye and ear problems.
- ☐ Changes in the way the heart and lungs work, diarrhoea or constipation, being sick (vomiting), abdominal (tummy) pain, loss of appetite, difficulty swallowing, tight or stiffening muscles, pain in the muscles, joints, neck and back.

OTHER RISKS:

- ☐ The reduced function of the immune system may lead to the development or reactivation of infections. Hepatitis B viral (HBV) infection may be reactivated during or after rituximab treatment. You may be a chronic carrier of the virus or have had an active HBV infection in the past. Reactivation may occur even with a resolved HBV infection status.
- ☐ Rituximab may very rarely cause severe skin reactions, progressive multifocal leukoencephalopathy (PML) or posterior reversible encephalopathy syndrome (PRES).
- ☐ Cancer can increase your risk of developing a blood clot (thrombosis), and having treatment with anti-cancer medicines may increase this risk further. A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain - you must tell your doctor straight away if you have any of these symptoms.
- ☐ Some anti-cancer medicines can damage women's ovaries and men's sperm. This may lead to infertility in men and women and/or early menopause in women.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant while you are having treatment and for 12 months afterwards. It is important to use effective contraception during and for 12 months after treatment. You can talk to your doctor or nurse about this.
- ☐ Very rarely complications of treatment with anti-cancer medicines can be life-threatening or even result in death. The risks are different for every individual. You can talk to your doctor or nurse about what this means for you.

STATEMENT OF HEALTH PROFESSIONAL (continued)

Patient identifier/label

ANY OTHER RISKS:

_____

_____

_____

_____

☐ **I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.**

☐ **I have discussed the intended benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.**

THE FOLLOWING LEAFLET HAS BEEN PROVIDED:

☐ Information leaflets for rituximab.

☐ 24 hour chemotherapy service contact details

☐ Other, please state: _____

_____

_____

Signed: _____ Date: _____

Name (PRINT): _____

Job title: _____

STATEMENT OF INTERPRETER (where appropriate)

INTERPRETER BOOKING REFERENCE (if applicable): _____

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed: _____ Date: _____

Name (PRINT): _____

Job title: _____

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 the form 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 and 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 training and experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to 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:

Patient's signature: _____ Date: _____

Name (PRINT): _____

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 (see notes).

Parent's/Witness' signature: _____ Date: _____

Name (PRINT): _____

COPY ACCEPTED BY PATIENT: YES / NO

(please circle)

CONFIRMATION OF CONSENT

(health professional to complete when the patient attends for treatment, 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 advance decision to refuse treatment

☐ Patient has withdrawn consent
(ask patient to sign /date here)

Signed: _____

Date: _____

FURTHER INFORMATION FOR PATIENTS

CONTACT DETAILS (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone **0808 800 4040**, Monday to Friday, 9am to 5pm. Alternatively visit **www.cruk.org** for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

GUIDANCE FOR HEALTH PROFESSIONALS

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

WHAT A CONSENT FORM IS FOR

This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

THE LAW ON CONSENT

See the Department of Health's Reference guide to consent for examination or treatment 2nd Edition for a comprehensive summary of the law on consent (also available at **www.doh.gov.uk**).

WHO CAN GIVE CONSENT

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will have capacity to give consent for himself or herself. Young people aged 16 and 17, and younger children with capacity, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

WHEN NOT TO USE THIS FORM

If the patient is 18 or over and lacks the capacity to give consent, you should use an alternative form (form for adults who lack the capacity to consent to investigation or treatment) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so.

Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

INFORMATION

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

REFERENCES

1. Summary of Product Characteristics (SPCs) for individual drugs: https://www.medicines.org.uk/emc/
2. Cancer Research UK: http://www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/cancer-drugs/
3. Macmillan Cancer Support, Cancer Information: http://www.macmillan.org.uk/Cancerinformation/Cancertreatment/Treatmenttypes/Chemotherapy/Chemotherapy.aspx
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent forms.