Patient agreement to systemic anti-cancer therapy (SACT)

R-CODOX-M / R-IVAC

Hospital/NHS Trust/NHS Board:

_____

Responsible Consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____

(or other identifier)

Special requirements:
(e.g. other language/other communication method)

Name of proposed course of treatment (include brief explanation if medical term not clear)

☑ Rituximab, Cyclophosphamide, Vincristine, Doxorubicin, Cyclophosphamide, Methotrexate, Cytarabine (R-CODOX-M) / Rituximab, Ifosfamide, Etoposide, Cytarabine, Methotrexate (R-IVAC) for adult B-cell non-Hodgkin lymphoma.

☑ **R-CODOX-M (usually cycles 1 and 3):** Rituximab and Doxorubicin intravenously on day 1. Cyclophosphamide intravenously on days 1 - 5. Vincristine intravenously on days 1 and 8. Methotrexate intravenously on day 10. Cytarabine by **intrathecal** injection on days 1 and 3. Methotrexate by **intrathecal** injection on day 15. **If applicable:** cycle 1 only additional **intrathecal** Cytarabine on day 5 and **intrathecal** Methotrexate on day 17.

☑ **R-IVAC (usually cycles 2 and 4):** Rituximab intravenously on day 1 (scheduling as per local protocol). Etoposide and Ifosfamide intravenously on days 1 to 5. Cytarabine intravenously on days 1 and 2. Methotrexate by **intrathecal** injection on day 5. **If applicable:** cycle 2 only additional **intrathecal** Cytarabine on days 7 and 9.

☑ Timing of intrathecal treatment may be changed as per local policy. A separate consent form must be completed for intrathecal treatment.

☑ The next treatment cycle will start when blood counts are in range. Treatment is continued for 4 cycles.

☑ Growth factors (G-CSF) subcutaneously according to local protocol. Intravenous Mesna to protect the bladder from irritation with Ifosfamide. Calcium Folinate (Folinic Acid) intravenously to prevent severe Methotrexate side effects (may also be given orally). Sodium bicarbonate intravenously and/or orally to help the kidneys remove Methotrexate.

Where will I have treatment?

☐ 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/NHS board's consent policy)

☑ Tick all relevant boxes

☑ I confirm the patient has capacity to give consent.

☑ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

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

☐ Remission induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☑ An increased risk of getting an infection from a drop in white blood cells and reduction in antibody levels – it is harder to fight infections and you can become very ill.
- ☑ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☑ Tiredness and feeling weak (fatigue).
- ☑ Feeling sick (nausea), being sick (vomiting). You will be given anti-sickness medication to prevent this (side effects include diarrhoea, constipation, headaches).
- ☑ Diarrhoea, constipation, tummy cramps.
- ☑ Appetite loss, taste changes, weight changes.
- ☑ Sore mouth/throat or ulcers (which can be severe).
- ☑ Hair thinning or loss.
- ☑ Skin itch, colour changes, thickening, sensitivity to sunlight (may last for several months),
- ☑ Sore hands and feet (sometimes change in colour and peeling may develop), nail changes.
- ☑ Numbness or tingling in hands and feet (usually mild and temporary), burning sensation, reduced sensation, nerve pain. Tell your doctor if you have persistent pain or find it hard to fasten buttons or do other fiddly tasks, as treatment doses may need to be adjusted. Rarely these symptoms (neuropathy) can be long term or permanent.
- ☑ Aches, pain, weakness in the muscles and joints, jaw pain, difficulty walking, feeling unsteady
- ☑ Bruising or bleeding (due to low platelets).
- ☑ Anaemia (low red blood cells) causing tiredness, fatigue, shortness of breath.
- ☑ Intravenous Methotrexate and Ifosfamide can damage the kidneys. You will have medicines to prevent this. Your kidneys will be monitored with blood and urine tests. You will have Methotrexate levels measured.
- ☑ Changes in liver function (rarely this may be severe) – monitored with blood tests.

Common side effects continued:

- ☑ Pink-red urine due to Doxorubicin, irritation of the bladder lining causing blood in the urine, pain while passing urine.
- ☑ Cytarabine syndrome may happen a few hours after having Cytarabine, causing fever or chills, rash, pain in the eyes, bones, tummy or chest.
- ☑ Inflammation of the lining of the eye lids (conjunctivitis) causing sore, red, itchy eyes. You will have steroid eye drops during and after Cytarabine to prevent this.
- ☑ Reactions may happen while Rituximab is being given or soon after. They are usually most noticeable with the first infusion: flu-like symptoms, back pain, high or low blood pressure, flushing, breathlessness, feeling or being sick, faster or irregular heartbeat. Rituximab, Methotrexate and Etoposide may also cause allergic reactions.
- ☑ Build-up of fluid causing weight gain.
- ☑ Changes in the lungs (inflammation or scarring) causing shortness of breath, chest pain, cough.
- ☑ High dose Cytarabine therapy, Methotrexate, (and less commonly Ifosfamide) may cause temporary (or occasionally permanent) changes to the nervous system causing: seizures (fits), drowsiness, unsteadiness, mood changes, dizziness and headaches. You will be monitored for these symptoms and treatment may be given to help with them.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☑ A mild reaction at the injection site (ache or colour changes), red or dark streaks along the vein with Doxorubicin, skin peeling or ulcers.
- ☑ Reduction in heart function due to heart muscle becoming thickened or stiff (cardiomyopathy), which may be permanent, irregular heart beat, high or low blood pressure.
- ☑ Hearing changes (ringing in the ears, changes in hearing and uncommonly high frequency hearing loss which may be permanent). Tell your doctor if you notice any changes in your hearing.
- ☑ Rituximab can increase your blood sugar levels.
- ☑ Watering, red eyes, vision changes, stuffy or runny nose.
- ☑ Ulcers involving the bowel.

Continue on to the next page

Statement of health professional

Patient identifier/label

Occasional side effects continued:

- ☑ Sweating, night sweats, difficulty sleeping, anxious.
- ☑ Increased risk of a second cancer (years later), particularly of the blood.

Other risks:

- ☑ Any drug given through a vein may leak out the vein and some may damage tissue around it while being given (extravasation). Leaks may cause stinging, pain, skin colour changes, swelling by the vein. Tell the nurse straight away if you have any of these symptoms. It's uncommon but important to deal with quickly.
- ☑ A risk of tumour lysis syndrome (when treatment destroys cancer cells too quickly for the kidneys to cope). You may be prescribed medicines for prevention or treatment. Rarely, dialysis may be needed
- ☑ Before treatment, you will have blood tests to check for viruses such as Hepatitis B, Hepatitis C, HIV or more unusual infections. This treatment may weaken your natural defence (immune) system making you prone to infections, or, existing infections could worsen or become active again if you've had them in the past. You may be given medicines to prevent or treat infection.
- ☑ Growth factor injections (G-CSF) are given to maintain white blood cells and reduce infection risk. They may cause bone pain, headaches, red and itchy skin around the injection site.
- ☑ Rituximab rarely cause severe skin reactions, causing sore red patches which blister and peel (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis). Methotrexate may make your skin more sensitive to the sun. This can look like severe sunburn. Protect your skin from sunlight.
- ☑ Rituximab may very rarely lead to a serious brain infection (Progressive Multifocal Leukoencephalopathy) and for Methotrexate (leukoencephalopathy). Tell your doctor or nurse immediately if you notice confusion, memory loss, trouble thinking, difficulty walking, vision changes, weakness on one side of your body.
- ☑ Rare side effects of Methotrexate include: inflammation of the lining around the heart, build-up of fluid around the heart, seizures, vision changes and feeling depressed.

Other risks continued:

- ☑ Rituximab rarely causes a break or hole in the digestive tract (perforation). Tell your doctor if you have sudden intense tummy pain or blood in the vomit or stools.
- ☑ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, skin colour changes and swelling in an arm or leg, and/or breathlessness or chest pain. Tell your doctor straight away if you have any symptoms.
- ☑ Changes in memory, concentration, ability to think clearly. There can be many causes, including your treatment, diagnosis or both.
- ☑ Complications of treatment can occasionally be severe and need intensive care support, or be life-threatening and result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side-effects may also be life-threatening.
- ☑ Following treatment, the lymphoma may either persist (rarely), or return after a period of time. Different treatment may then be needed if this is appropriate for you.

If applicable:

- ☑ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☑ Some anti-cancer medicines may damage development of a baby in the womb or cause problems with pregnancy and birth. It is important not to become pregnant or make someone else pregnant during treatment and for 12 months after. or make someone else pregnant during. Use effective contraception.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☑ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☑ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☑ 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 explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☑ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☑ Information leaflet for R-CODOX-M / R-IVAC

☑ 24 hour alert card or SACT advice service contact details

☑ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

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

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

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 have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

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 that the patient has no further questions and wishes the course of treatment/procedures 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 and 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 its 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 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.

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 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 checklist 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 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 following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (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. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. 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 lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- 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 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. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if 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.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
   Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form