Patient agreement to systemic anti-cancer therapy (SACT): FCR (Fludarabine-Cyclophosphamide-Rituximab) 5 days

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

☐ Fludarabine, cyclophosphamide, and rituximab for the treatment of chronic lymphocytic leukaemia (CLL).

☐ Fludarabine, cyclophosphamide and rituximab are given in combination every 28 days for 6 cycles.

☐ Fludarabine capsules and cyclophosphamide tablets are taken orally each day on days 1-5. AND

☐ Rituximab is given by intravenous infusion on day 1 of each treatment cycle. For the first cycle the dose may be given the day before fludarabine and cyclophosphamide and split across 2 consecutive days.

Where the treatment will be given:

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: ______________________________________

Person may be treated as an outpatient if the treatment is given over two days, with the patient separated into two different episodes of care. Each episode of care must last for at least 24 hours and must not be interrupted by an interval of less than 24 hours.

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

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

☐ DISEASE CONTROL - The aim is not to cure but to control the disease and reduce the symptoms.

☐ To obtain or maintain remission of your leukaemia, in order to improve both quality and quantity of life.
Statement of health professional
(continued)

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:

- Bruising and bleeding, anaemia (low number of red blood cells), tiredness and feeling weak (fatigue), feeling sick (nausea) and being sick (vomiting), diarrhoea, constipation, sore mouth and ulcers, and taste changes.

- 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 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)

Infusion-related side effects may occur during or within 1-3 hours of rituximab infusion. These include flu-like symptoms (high temperature, chills, muscle aches, tiredness, dizziness and headache), low blood pressure, flushing, and allergic reactions (signs include skin rashes, itching, feeling of swelling in the tongue or throat, irritation of the nasal passages, wheezing, coughing and breathlessness). They are most noticeable with the first infusion.

- Fludarabine may cause severe lymphopenia, render you susceptible to transfusion-associated graft versus host disease, and complications of blood transfusions. Irradiated blood components are recommended for blood transfusions.

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

- Loss of appetite, skin changes, nail changes, and numbness or tingling in the fingers and toes.

- An increased risk of developing a second cancer.

- 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.

Other risks:

- There may be a risk of tumour lysis syndrome in the presence of a high tumour burden. Symptoms are caused by the breakdown of cancer cells when treatment is started. Patients who are at a high risk will be prescribed medicines to reduce the risk of complications.

- FCR can reduce the function of the immune system. This can lead to the development of infections. You may be prescribed medicines to prevent and/or protect you from the risks and complications of infections. Viral infections, including hepatitis B (HBV) may be reactivated during or after treatment.

- Other side effects include changes to the lungs and changes in the way the heart works.

- Potential side-effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation.

- 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 or father a child and to use effective contraception while you are having treatment and for 12 months afterwards. You can talk to your doctor or nurse about this.
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):

The following written information has been provided:

☐ Information leaflet for FCR or the individual drugs (fludarabine, cyclophosphamide and rituximab).

☐ 24 hour alert card or SACT advice service contact details

☐ SACT record booklet / diary

☐ 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 patient to the best of my ability and in a way in which I believe they can understand.

Signed: ___________________________________________ Date: __________________________

Name (print): ____________________________________________

Job title: ____________________________________________

TO BE RETAINED IN PATIENT NOTES
Prepared by Pharmacist: Victoria Fashina
Checked by Pharmacist: Llywelyn Cadman-Davies
Checked by Consultant: Piers Patten
Date of issue and version: Jun-19; Version 1;
Review date: Jun-22
Approved by: Janine Mansi (UK Chemotherapy Board)
Check www.cruk.org/sact_consent for latest version
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 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. Young people/children may also like a parent to sign here (see notes).

Patient’s signature: __________________________ Date: ________________
Name (print): ______________________________

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 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 /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 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.

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Guidance for health professionals
(to be read in conjunction with the hospital’s consent policy)

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 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 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 2008 (available at www.gmc-uk.org/guidance), and Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (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 the child 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, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where children are able to give consent for themselves, 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). 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 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 (SmPCs) for individual drugs: https://www.medicines.org.uk/emc
4. Guy’s and St. Thomas’ NHS Foundation Trust, Chemotherapy consent forms

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