Patient agreement to systemic anti-cancer therapy (SACT)

Tecartus CAR T-Cell Therapy for Relapsed or Refractory B Cell ALL (26 Years and Over)

Hospital/NHS Trust/NHS Board:

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Responsible consultant:

Name: ____________________________

Job title: ___________________________

Patient details

Patient’s surname/family name:

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Patient’s first name(s): ______________

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Date of birth: ______________________

NHS number: ______________________

(or other identifier)

Special requirements:
(eg other language/other communication method)

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

☐ Cyclophosphamide, Fludarabine and Chimeric Antigen Receptor T-cell (CAR T-cell) therapy (Brexucabtagene Autoleucel, Tecartus) for relapsed or refractory B cell acute lymphoblastic leukaemia (ALL) in patients aged 26 years and over.

☐ **Leukapheresis:** a sample of T-cells (white blood cells that form part of your immune system) are taken from your blood in a process called leukapheresis. They are sent to a laboratory where they are genetically modified to become CAR T-cells which recognise your cancer cells. A separate consent form will be completed for this.

☐ **Bridging therapy:** the CAR T- cell production process takes a few weeks. You may need steroids, chemotherapy, immunotherapy, radiotherapy or a combination of these treatments in this time to control your leukaemia (a separate consent form must be completed if bridging therapy is used).

☐ **Lymphodepletion chemotherapy:** Cyclophosphamide and Fludarabine chemotherapy will then be given to reduce your remaining T-cells. This helps your body to accept the new CAR T-cells. They are given intravenously over a few days before you have the CAR-T infusion (Tecartus). The timing and location of this depends on local policy.

☐ **CAR T-Cell infusion:** The CAR T-cells (Tecartus) are given by a single intravenous infusion. This is a single treatment which will not be repeated.

Where will I have treatment?

☐ You will usually need to be admitted to hospital and stay there for at least seven days after your CAR T-cell infusion. This may be for longer if you do not live close to the hospital, or if you do not have a caregiver who can look after you at all times in the first month after treatment.

☐ After you are discharged from hospital, you will need to come to the hospital and/or be contacted by telephone multiple times each week for at least the first month after treatment. This is so that doctors and nurses can closely monitor you. You will have a bone marrow biopsy to see how well your disease has responded to this treatment.

Patient identifier/label

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)

☐ The aim of this treatment is to control the leukaemia for as long as possible, improving quality and quantity of life.

☐ Most patients respond to this treatment. For patients who respond very well to treatment, this response may last for years. For some patients, this response may be much shorter and last for months. Some patients do not respond at all. In this case, further treatments for leukaemia may be limited by the treatments that have been used before.

☐ In some cases, your leukaemia may progress quickly before the CAR T-cells are ready to be infused. You may become too unwell to continue with this treatment.

☐ In a small number of patients, there are difficulties manufacturing the CAR T-cells. Proceeding with a lower dose of CAR T-cells, another attempt at leukapheresis or a different treatment option may be tried.

You may have one or more of the side effects listed below

Fludarabine and Cyclophosphamide

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 – it is harder to fight infections and you can become very ill.

☐ **If you have an 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)**

☐ Anaemia (low red blood cells), bruising and bleeding (due to low platelets). If you need to have a blood or platelet transfusion, these will be irradiated to prevent a rare reaction.

☐ Tiredness, feeling weak (fatigue), fever, cough.

☐ Pain when passing urine, blood in the urine.

☐ Thinning of the hair or hair loss, skin rash.

☐ Feeling sick (nausea), being sick (vomiting), diarrhoea, sore mouth and ulcers, appetite loss.

Occasional side effects

Affecting between 1 and 10 in every 100 (1-10%):

☐ A risk of a second cancer (years later).

☐ Changes in how well the liver works (monitored with blood tests).

Occasional side effects continued:

☐ Numbness and tingling in hands and feet, aches and pain in muscles and joints, build-up of fluid.

Other risks:

☐ Rarely, changes in the lungs (inflammation or scarring), changes in how well the heart works, irregular heart rhythm, severe skin reactions.

☐ Anti-sickness medicines may cause constipation, headache, indigestion, sleep problems, agitation.

☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell a nurse straight away if you have stinging, pain, redness, swelling around the vein. It's uncommon but important to deal with quickly.

☐ You will have blood tests to check for viruses (Hepatitis B, Hepatitis C, HIV or more unusual infections). This treatment and CAR T-cell therapy may weaken your natural defence (immune) system making you prone to infections. Existing infections may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.

☐ Complications of treatment can occasionally be life-threatening and may 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.

Patient identifier/label

Statement of health professional CAR T-Cell Therapy

☐ Tecartus is a new treatment, so not all side effects are known about yet. Some happen during treatment, but can also happen months later. Tell your treatment team as soon as you develop any side effects. It’s important to treat them when they happen so they don’t get worse.

☐ Serious side effects are usually reversible. You may need admission to intensive care (for monitoring and organ support) and treatment with anti-inflammatory medicines and steroids.

☐ Considering your individual health, we anticipate the risk of intensive care unit (ICU) admission to be _______%.

☐ Considering your individual health, we anticipate the risk of not surviving as a direct result of a treatment side effect to be _______%.

During admission and first few months:

☐ Cytokine Release Syndrome (CRS) is a common immune response. It usually happens in the first week, but can happen later. It is usually mild but can be severe in up to a quarter of patients, which may potentially be life-threatening. It may lead to excessive inflammation, effects on different organs and low blood cell counts.

- **Contact your treating team right away if you have: a fever, tiredness, shortness of breath, feeling or being sick, diarrhoea, fast heartbeat, low urine output, headache**

☐ Effects on the brain are common (neurotoxicity or ‘ICANS’). They usually happen in the first two weeks, but can happen later. They can be mild to moderate or more severe in up to a third of patients, causing confusion, seizures, coma.

- **Contact your treating team right away if you have: confusion, tremors, difficulty speaking, difficulty understanding speech, dizziness, agitation, drowsiness, handwriting changes**

☐ An increased risk of an infection during and after treatment, which may be more severe if there is a drop in your white blood cell count - it is harder to fight infections and you can become very ill.

☐ **If you have an 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)**

☐ Allergic reactions may happen while treatment is being given or shortly afterwards.

☐ A risk of tumour lysis syndrome (when treatment destroys cancer cells too quickly for the kidneys to cope). Rarely, dialysis may be needed. You will be prescribed medicines for prevention.

☐ Commonly in the first few weeks: anaemia (low red blood cells) causing tiredness, low platelets causing bruising or bleeding, low white blood cell counts increasing your risk of infections. You may need blood or platelet infusions or injections to increase white blood cell counts.

☐ You must not drive or operate machinery for 8 weeks after CAR-T cell infusion (or longer if neurological symptoms continue).

Ongoing and long term side effects:

☐ An increased risk of infection. You will have medicines to prevent infection in the months after treatment. You will need to have some vaccines again. Your doctor will tell you more about this.

☐ Treatment may cause low levels of protective antibodies in the blood and lead to repeated infections. If this continues, regular antibody infusions may be needed on a long-term basis.

☐ Low blood counts may last for months and need blood transfusions or injections to increase blood cell counts. Sometimes, more intensive treatment is needed.

☐ A risk of a second cancer (years later).

Other risks:

☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.

☐ Some anti-cancer medicines can damage ovaries / sperm leading to infertility / early menopause.

☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and afterwards. Use effective contraception during treatment and for one year after treatment.

☐ Complications of treatment can occasionally be life-threatening and may 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.

Statement of health professional

Patient identifier/label

Any other relevant information, including risks specific to the individual:

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☐ 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): ______________________________

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☐ I have explained that the patient will be monitored for at least 15 years post CAR T-cell infusion and that, with their consent, data about the patient's treatment will be submitted to the European Society for Blood and Marrow Transplantation Registry for monitoring (separate written consent form).

☐ I have explained that data will be collected and analysed by national registries for research purposes.

Clinical management guideline/Protocol compliant (please tick):

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

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The following written information has been provided:

☐ Information leaflets for CAR T-cell therapy, Cyclophosphamide, Fludarabine and Tecartus patient alert card

☐ 24 hour alert card or SACT advice service contact details

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

☐ Irradiated blood product alert card

Health professional details:

Signed: ____________________

Date: ____________________

Name (PRINT): ____________________

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Job title: ____________________

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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: ____________________

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.

☐ I agree to data relating to my diagnosis, treatment and outcomes being submitted and analysed by national registries for research purposes for the benefit of future patients.

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):

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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.

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 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 (www.gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (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. 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: www.medicines.org.uk/emc
2. Cancer Research UK: www.cancerresearchuk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: www.macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form