Patient / parent / guardian agreement to systemic cancer therapy for Acute lymphoblastic leukaemia / lymphoma in children and young people

Hospital name: _____

_____

Responsible health professional:

Name: _____

Job title: _____

Patient details (label)

Surname: _____

_____

First name(s): _____

_____

Date of birth: _____

NHS number/local identifier no:

_____

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

_____

_____

_____

Indication for treatment (diagnosis):

- ☐ Acute lymphoblastic leukaemia
- ☐ Lymphoblastic lymphoma
- ☐ Mixed phenotype acute leukaemia

Name of proposed course of treatment:

- ☐ ALLTogether-1 Trial Protocol (excluding high risk blocks 1-3, antibody therapy, chimeric antigen receptor T-cell therapy or haematopoietic stem cell transplant).
- ☐ UK ALL Treatment Guideline (please specify):

_____

_____

- ☐ Other (please specify): _____

_____

Participation in a formal clinical trial:

☐ Yes ☐ No ☐ Decision awaited

If yes, trial name:

- ☐ ALLTogether-1 Study
- ☐ Other (please specify): _____

_____

If no, specify reason: _____

_____

_____

(A trial specific consent form must be signed in addition to this form, for any patient on a clinical trial)

Intention of the proposed treatment plan:

- ☐ Curative – given with intent of cure
- ☐ Other (please specify): _____

The following drugs may be included in your / your child's treatment (tick all that apply):

- ☐ Asparaginase
- ☐ Cyclophosphamide
- ☐ Cytarabine
- ☐ Daunorubicin
- ☐ Doxorubicin
- ☐ Methotrexate
- ☐ 6-Mercaptopurine
- ☐ 6-Thioguanine
- ☐ Vincristine
- ☐ Steroid: _____
- ☐ Other (not listed):

_____

Treatment information
(continued)

Patient identifier/label

You/your child might have treatment via the following routes (tick all that apply):

- ☐ Intravenous (into the bloodstream)
- ☐ Oral (by mouth)
- ☐ Intrathecal (injection into the spinal fluid)*
- ☐ Intraventricular (injection into the spaces in the brain)*
- ☐ Intramuscular (injection into a muscle)

*Information and consent will be on a separate form

Treatment will be delivered in the following settings and locations (tick all that apply):

- ☐ Principal Treatment Centre
- ☐ Paediatric Oncology Shared Centre (POSCU) (specify name):

_____

- ☐ TYA designated hospital (specify name):

_____

- ☐ Home ☐ Inpatient ☐ Outpatient
- ☐ Other (please specify): _____

The total duration of treatment will be approximately:

☐ 108 weeks (ALLTogether-1) ☐ Other (please specify): _____

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 have explained the course of treatment to patient/parent/legal guardian. In particular, I have explained the potential side effects of the treatment.

Significant, unavoidable or frequently occurring risks (tick all that apply):

Immune System / Blood System:

- ☐ There is an increased risk of developing serious infections when on treatment. Your doctor or nurse will give you guidance on when to contact them. **Please follow these instructions carefully and always seek medical attention if:**
  - **You/your child has a fever over 38°C**
  - **You/your child suddenly feels unwell (even with a normal temperature)**
  - **You/your child has been in contact with a case of chicken pox or measles**
- ☐ Anaemia (low red blood cells which may cause tiredness, breathlessness, dizziness or looking pale).
- ☐ Bruising and bleeding due to low platelets.
- ☐ Need for blood and platelet transfusions.
- ☐ Blood clots (thrombosis) – Cancer and anti-cancer therapy increases the risk of developing these. They most commonly occur in blood vessels of the brain (cerebral venous sinus thrombosis), around a central venous access device, in the leg (deep vein thrombosis) or in the lung (pulmonary embolus).
- ☐ Allergic reactions including anaphylaxis. These can be life-threatening.

Gastro-Intestinal System (including liver and pancreas):

- ☐ Feeling sick or being sick (nausea/vomiting).
- ☐ Abdominal (tummy) pain.
- ☐ Diarrhoea.
- ☐ Constipation.
- ☐ Heartburn/indigestion.
- ☐ Increased or decreased appetite and temporary weight gain/loss.
- ☐ Change of taste.
- ☐ Sore mouth (mucositis).
- ☐ Need for nutritional support – drink supplements or nasogastric tube feeds.
- ☐ Pancreatitis (inflammation of the pancreas causing abdominal pain and/or vomiting).
- ☐ Changes meaning your liver does not work properly

Neurological System (including brain/peripheral nerves and senses):

- ☐ Mood swings, which may sometimes be severe.
- ☐ Changes meaning your brain does not work properly (encephalopathy, fits/seizures, stroke like syndrome and/or changes in level of consciousness).
- ☐ Changes in how your brain works (concentration and learning) – can sometimes be permanent.
- ☐ Neuropathy – pain, numbness, tingling and/or weakness due to nerve damage. This usually affects the legs, hands and feet.
- ☐ Nerve damage to the vocal cords – symptoms can include pain, hoarseness, loss of voice or breathing difficulties.
- ☐ Muscle weakness and difficulty swallowing.

Significant, unavoidable or frequently occuring risks

(continued)

Patient identifier/label

Cardiovascular System (including heart and blood vessels):

- ☐ Changes meaning your heart does not work properly.
- ☐ High blood pressure.
- ☐ Fluid retention.

Respiratory System (lungs):

- ☐ Changes meaning your lungs do not work properly.

Urinary System (including kidneys and bladder):

- ☐ Tumour lysis syndrome – Abnormal salt levels in the blood and in some cases kidney damage, caused by the breakdown of cancer cells.
- ☐ Changes meaning your kidneys do not work properly.
- ☐ Inflammation of the bladder causing blood in the urine and difficulty passing urine.
- ☐ Kidney stones.
- ☐ Electrolyte (salt) levels can become too low or too high.

Endocrine System (including hormones):

- ☐ Unstable blood sugars including temporary diabetes.

Skin (including hair):

- ☐ Hair loss.
- ☐ Rashes, acne, stretch marks and dry skin.
- ☐ Extravasation – some anti-cancer therapy can cause severe damage to the skin (burn) if they leak under the skin when injected using a needle or cannula.

Growth and Development:

- ☐ Imparied bone growth and development.
- ☐ Osteonecrosis – bone damage due to disruption of blood supply to bone.

Fertility and Pregnancy:

- ☐ Anti-cancer treatment can pose a risk to reproductive organs and may, in later life, lead to infertility and early menopause. The majority of children and young people with leukaemia whose disease is cured with first line treatment and does not relapse will retain fertility into adulthood.
- ☐ Some anti-cancer drugs can damage the development of a baby in the womb. It is important not to become pregnant or make some someone else pregnant while you are having treatment or for 12 months afterwards. If appropriate, it is important to use effective contraception throughout this period.

Other:

- ☐ Anti-cancer treatment increases the risk of developing other cancers when older (secondary cancers). This risk is small with ALL therapy.
- ☐ The complications of treatment with anti-cancer medications can be life-threatening and can rarely result in death.
- ☐ Other (please specify): _____

_____

_____

Statement of health professional

- ☐ I have discussed the intended benefits of the treatment advised and risks of any available alternative treatments (including no treatment).
- ☐ I have discussed the side effects of the treatment advised, 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) and location.

The plan outlined above is recommended as offering the best choice of treatment, however, this is not a guarantee that the treatment will be effective against leukaemia/lymphoma in the future and there is a chance the leukaemia/lymphoma may not respond adequately to the treatment or may return (relapse) in the future. In such situations, alternative treatment options may be available and your clinical team would discuss these with you at the time.

The following additional information has been supplied:

_____

Clinical nurse specialist (CNS)/keyworker contact: _____

Written information provided (please specify): _____

Statement of patient/parent/ legal guardian:

Patient identifier/label

Please read this form carefully. You will be offered a copy. If you have any questions, please ask. We are here to help you. You have the right to change your mind at any time including after you have signed the form.

- ☐ I confirm I am the patient/person with parental responsibility for the patient/person named on this form. (delete as appropriate)
- ☐ **I agree** to the treatment described on this form.
- ☐ I understand that any procedures, in addition to any described on this form, will only be carried out if it is necessary to save my life/my child's life or to prevent serious harm to my/my child's health.
- ☐ I have been told about additional procedures which may become necessary during the period of treatment. I have listed below any procedures which I do not wish to be carried out without further discussion:

_____

Patient/parent/legal guardian (delete as appropriate)

Signature: _____ Date: _____

Name (PRINT): _____

A witness should sign below if the parent/guardian is unable to sign but has indicated their consent.

Witness signature: _____ Date: _____

Name (PRINT): _____

Where a parent/legal guardian has signed this form, the young person named on the form is invited to sign below to indicate their agreement or assent to the treatment outlined above:

Young persons' signature: _____ Date: _____

Name (PRINT): _____

Copy accepted by patient/parent/legal guardian : ☐ Yes ☐ No (please tick)

Statement of interpreter (where appropriate)

Interpreter booking reference (if applicable): _____

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

Signature: _____ Date: _____

Name (PRINT): _____

Job title: _____

Statement of patient/parent/ legal guardian:
(continued)

Patient identifier/label

Health care professional obtaining consent:
(complete before treatment starts)

I have explained the treatment to the patient/ parents/legal guardian including the intended benefits and side effects as indicated above.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Additional information:

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

Set out below is some additional information that may be useful during the course of the proposed treatment.

Emergency contact information:

The following information should be used to contact your treating team if needed

Normal working hours (Mon-Fri): 09:00-17:00 _____

Normal working hours (Sat/Sun): 09:00-17:00 _____

Out of hours (evening/nights): 17:00-09:00 _____

The space below is purposefully left blank to allow you to record any information in addition to, but not part of, the formal consent process:

Cancer Registration:

Upon a diagnosis of cancer, the NHS records information on you and your diagnosis through the National Cancer Registry which is part of NHS Digital (England), Public Health Scotland, Public Health Wales and the Public Health Agency (Northern Ireland). Cancer registration is the only way we can understand how many people are getting cancer, the types of cancer they have and the success of any treatments. Cancer registration also helps drive research into cancer and improving outcomes from cancer.

Any information is kept confidential and is secure.

You can opt out of cancer registration. Further information on Cancer Registration and how to opt-out can be found at: **www.digital.nhs.uk/ndrs (England), www.publichealthscotland.scot/our-areas-of-work/conditions-and-diseases/cancer/scottish-cancer-registry-and-intelligence-service-scris/ (Scotland), www.phw.nhs.wales/services-and-teams/welsh-cancer-intelligence-and-surveillance-unit-wcisu/ (Wales), www.publichealth.hscni.net/directorate-public-health/service-development-and-screening/northern-ireland-cancer-registry (Northern Ireland).**

This consent form has been developed by a multi-professional group working in the fields of children's and young adult cancer supported by the UK SACT Board, Cancer Research UK and the Children's Cancer and Leukaemia Group (CCLG).

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-memoire 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 2020 (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. 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.

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 (SmPCs) for individual drugs: https://www.medicines.org.uk/emc
2. Cancer Research UK: https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/cancer-drugs
3. Macmillan Cancer Support: https://www.macmillan.org.uk/information-and-support/treating/chemotherapy/drugs-and-combination-regimens
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent forms.