Patient/parent/legal guardian agreement to systemic anti-cancer therapy for children and young people

Hospital name: ____________________

____

Responsible health professional:

Name: ____________________

Job title: ____________________

Indication for treatment (diagnosis):

____

Name of proposed course of treatment
(Include brief explanation if medical term not clear. Include regimen/protocol name)

Regimen/protocol: ____________________

____

Patient details (label)

Surname: ____________________

____

First name(s): ____________________

____

Date of birth: ____________________

NHS number/local identifier no:

____

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

____

____

____

Participation in a formal clinical trial:

☐ Yes ☐ No

(A clinical trial-specific consent form will have been signed if the answer to the above question is 'Yes'. This form can be used in addition, to detail the side effects discussed if appropriate)

Trial name: ____________________

____

The following drugs are included in you/your child's treatment (Indicate all that apply):

- ☐ Asparaginase
- ☐ Bleomycin
- ☐ Busulfan
- ☐ Carboplatin
- ☐ Cisplatin
- ☐ Cyclophosphamide
- ☐ Cytarabine
- ☐ Dactinomycin
- ☐ Daunorubicin
- ☐ Doxorubicin
- ☐ Etoposide
- ☐ Fludarabine
- ☐ Gemtuzumab ozogamicin
- ☐ Idarubicin
- ☐ Ifosfamide
- ☐ Irinotecan
- ☐ Melphalan
- ☐ Mitoxantrone
- ☐ Mercaptopurine
- ☐ Methotrexate
- ☐ Rituximab
- ☐ Topotecan
- ☐ Vinblastine
- ☐ Vincristine
- ☐ Vinorelbine
- ☐ Steroids: ____________________

  ____
- ☐ Other (not listed)

  ____

  ____

  ____

Intention of the proposed treatment plan:

☐ Disease control and/or potential cure ☐ Disease control/palliative-with no expectation of cure

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)
- ☐ Subcutaneous (injection under the skin)
- ☐ Intramuscular (injection into a muscle)

The total duration of you/your child's treatment will be approximately: ____________________

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

☐ Principal Treatment Centre; ____________________

____

☐ Shared Care Unit/Paediatric shared care unit (POSCU):

____

____

☐ Home ☐ Inpatient ☐ Outpatient ☐ 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)

Patient identifier/label

☑ 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.

Immune system/blood system:

☐ There is an increased risk of developing serious infections when on treatment which can be life-threatening or result in death. Contact your treating team straight away if:

- **your temperature goes over 38°C**
- **you suddenly feel unwell (even with a normal temperature)**

Please contact your treating team if you think you have been in contact with a case of:

- **Chicken pox**
- **Measles**

☐ Anaemia (low number of red blood cells). You may need blood transfusion.

☐ Bruising/bleeding. You may need platelet transfusion.

☐ 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.

☐ Allergic reactions/ hypersensitivity.

Gastro-intestinal system (inc liver/pancreas):

☐ Feeling sick (nausea).
☐ Being sick (vomiting).
☐ Poor appetite.
☐ Change of taste.
☐ Need for nutritional support.
☐ Sore mouth (mucositis).
☐ Abdominal (tummy) pain.
☐ Diarrhoea.
☐ Constipation.
☐ Heartburn/indigestion.
☐ Inflammation of the pancreas.
☐ Impaired liver function/ veno-occlusive disease.

Neurological system (inc brain/ peripheral nerves and senses):

☐ Impaired brain function (fits/ seizures/changes in levels of consciousness/encephalopathy.
☐ Pain/numbness/tingling in hands/ feet/peripheries (neuropathy).
☐ Muscle weakness/mobility issues (neuropathy).
☐ Impaired hearing.
☐ Impaired vision.

Cardiovascular system (inc heart and blood vessels):

☐ Impaired heart function.
☐ Inflammation of hands/feet (vasculitis).
☐ High blood pressure.

Respiratory system (lungs):

☐ Impaired lung function.

Urinary system (inc kidneys/ bladder):

☐ Impaired kidney function.
☐ Inflammation within the bladder.
☐ Blood in the urine (haematuria).
☐ Tumour lysis syndrome.
☐ Electrolyte (salt) disturbances.

Endocrine system (inc hormones)

☐ Unstable blood sugar levels.
☐ Need for hormone replacement (e.g. thyroid/growth/steroid).

Skin (inc hair):

☐ Hair loss.
☐ Rashes.
☐ Dry skin.
☐ Nail changes.

Growth and development:

☐ Impaired brain function (concentration and learning)-this may be permanent.
☐ Impaired bone growth and development.
☐ Osteonecrosis-bone damage due to disruption of blood supply to the bone.

Fertility and pregnancy:

☐ Some anti-cancer therapy can affect the ability to have a baby in the future. For children who have not reached puberty it may be possible to freeze and store ovary or testicular tissue. As this is a relatively new technique, this procedure may be at a different hospital and can delay start of treatment. In some situations treatment may need to start quickly in which case the above procedure may not be possible.

☐ Some anti-cancer therapy may damage the development of a baby in the womb. It is important not to become pregnant or father a child whilst having treatment and for a few months afterwards. It is also important to use effective contraception during and after treatment. Speak to your doctor or nurse about this.

Other:

☐ There is an increased risk of developing other cancers when older (second cancers).

☐ Very rarely, the complications of treatment with anti-cancer therapy can be life-threatening or even result in death.

☐ Extravasation – Some anti-cancer therapy will cause damage to the skin (burn) if they leak under the skin when injected using a needle or cannula.

Statement of health professional

(continued)

Patient identifier/label

Other side effects (continued)

(Please list here other side effects or additional issues discussed at the time of consent for treatment, not listed above)

____

____

☐ 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 etc) 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 the cancer or that the cancer will not return (relapse) in the future. In such situations, alternative treatment options may be very limited or not available and may result in death from the cancer.

The following additional information has been supplied:

____

Clinical nurse specialist (CNS)/keyworker contact: ______________________________

Provided with treatment roadmap/flowsheet: ☐ Yes ☐ No

Statement of patient/parent/legal guardian:

Use of information, tissue and medical imaging for clinical and laboratory research:

a. I agree that tissue (including blood, urine and spinal fluid) not needed for my/my child's diagnosis or treatment can be used and stored for research which may include genetic research. ☐ Yes ☐ No

b. I agree that relevant sections of my/my child's medical record, including medical imaging, may be looked at by researchers, or by relevant regulatory authorities, where my/my child's tissue is being used for research. I give permission for these individuals to access my/my child's records. ☐ Yes ☐ No

c. I agree that data regarding my/my child's cancer may be shared in medical or scientific publications and at conferences with the purpose of improving outcomes for childhood cancer. I/my child would not be identifiable. ☐ Yes ☐ No

d. I/my child consent to partially anonymised clinical data being shared with regional/national/ international data collections, as appropriate, with the aim of improving patient outcomes. Partially anonymised data is data that cannot identify you as person by the holders of the data collections but the Trust would be able to link this back to the information that it holds about you/your child. ☐ Yes ☐ No

I understand that my/my child's initials and date of birth may be shared for this purpose.

e. I am happy to be approached by a research nurse about other studies that I/my child may be eligible for. ☐ Yes ☐ No

Tissue banking:

You are invited to consider donating tissue for research that may be left over following surgical procedures and/ routine tests that you will be having/have had to diagnose and/or treat your cancer. Any such remaining tissue will be stored in the designated Children's and Young People' Cancer Association (CCLG) Tissue Bank. Donated samples are only released for use in ethically approved research projects both in the UK and abroad that contribute to our understanding of cancers in children and young people or potentially improves the treatments we can offer.

Further information can be obtained by asking your local treating team or at the following website:
www.cclg.org.uk/tissue-bank/information-for-patients

Statement of health professional
(continued)

Patient identifier/label

Health care professional obtaining consent:

(Complete before patient starts treatment)

I have explained the treatment to the patient/parent/ 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 Public Health England. 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.ndrs.nhs.uk**

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 Chemotherapy Board, Cancer Research UK and the Children and Young People's Cancer Association (CCLG)

CCLG The Children & Young People's Cancer Association

CANCER RESEARCH UK

Statement of patient/parent/legal guardian

Patient identifier/label

Please read this form carefully. If treatment has been planned in advance, you may 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 confirm I am the patient/person with parental responsibility for the patient named on this form.

☐ I agree to the procedures and course of 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 me/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 signature: ______________________________ Date: ______________

____

Name (PRINT): ______________________________

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

Witness signature: ______________________________ Date: ______________

Name (PRINT): ______________________________

The young person named on the front of this form is invited to sign below indicating their agreement or assent to the treatment outlined above: ______________________________

Young person's 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.

Name (PRINT):______________________________

Job title:______________________________

Patient/parent/legal guardian signature: ______________________________ Date: ______________

Name (PRINT): ______________________________

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 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.

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.