Patient agreement to systemic anti-cancer therapy (SACT):

therapy (SACT):	Patient's first name(s):
Cetuximab-Carboplatin-	
Fluorouracil	Date of birth: NHS number: (or other identifier)
Hospital/NHS Trust/NHS Board:	Special requirements: (e.g. other language/other communication method)
Responsible consultant:	
Name:	
Job title:	
Name of proposed course of treatment (includ	e brief explanation if medical term not clear)
Cetuximab, carboplatin and fluorouracil chemoth	nerapy for the treatment of head and neck cancer.
☐ Cetuximab is given intravenously on day 1, 8 and 1 by continuous intravenous infusion on days 1 to 4. Th	1.5, carboplatin intravenously on day 1 and fluorouracil is is repeated every 21 days up to 6 cycles.
Cetuximab is continued as a single agent intrave appropriate) days until disease progression or unacc	
Where the treatment will be given	
☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐	Other:
Statement of health profession (to be filled in by health professional with appropriate knowled board's consent policy) Tick all relevant boxes I confirm the patient has capacity to give consent.	nal ge of proposed procedure, as specified in the hospital/Trust/NHS
I have explained the course of treatment and intende	d benefit to the patient.
The intended benefits (there are no guarantees abo	out outcome)
Curative – to give you the best possible chance of	being cured.
Disease control/palliative — the aim is not to cure improve both quality of life and survival.	out to control or shrink the disease. The aim is to
Adjuvant – therapy given after surgery/radiotherap	y to reduce the risk of the cancer coming back.

Neo-adjuvant – therapy given before surgery/radiotherapy to shrink the cancer, allow treatment and

Patient details

Patient's surname/family name:

reduce the risk of the cancer coming back.

Statement of health professional

(continued)

Significant, unavoidable or frequently occurring risks

organity and ordanic or modulating observing	
Common side effects: More than 10 in every 100 (>10%) people have one or more of the side effects listed: 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 lifethreatening. Contact your doctor or hospital straight away if:	Other risks: Carboplatin or fluorouracil may leak outside of the vein and damage the tissue around while being given (extravasation). Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein as although extravasation is uncommon, it's important that this is dealt with quickly.
 your temperature goes over 37.5°C or 38°C, depending on the advice given by your chemotherapy team you suddenly feel unwell (even with a normal temperature) 	 Fluorouracil can rarely cause heart problems (e.g chest pain, heart attack), confusion and unsteadiness. Allergic reactions with carboplatin is not common. There is a risk of potentially life-threatening side-
Thinning of the hair or hair loss, sore mouth and ulcers, nose bleed (may become severe), loss of appetite, change in taste, weight loss, feeling sick (nausea) and being sick (vomiting), abdominal (tummy) pain, tiredness and feeling weak (fatigue),	effects if your genetic make-up is such that you cannot break down fluorouracil properly. This is called DPD deficiency. Please contact your doctor or nurse straight away if you get even minor side-effects in your first cycle of treatment.
watery diarrhoea. Cetuximab specific: skin reactions (e.g. acne-type rashes, dry and itchy skin, scaling), increase in hair	Potential side-effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation.
growth, nail changes. Changes in heart rhythm, low electrolyte levels (magnesium, potassium, sodium, calcium), kidney and liver function changes.	Steroids and fluorouracil can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels. Please ask your doctor/nurse/GP if concerned.
Cetuximab may cause a flu-like reaction while it's being given and for several hours afterwards. It is usually mild but, rarely can be more severe. You will have medicines before to help prevent this.	Very rarely cetuximab causes severe skin reactions which can subsequently blister and peel, please seek urgent medical advice. This is called Toxic Epidermal Necrolysis or Stevens Johnson Syndrome.
Fluorouracil specific: soreness and redness of the palms of the hands and soles of the feet (hand-foot syndrome), slow wound healing.	Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain or stroke. Tell your
Occasional side effects: Between 1 and 10 in every 100 (1-10%) people have one or more	doctor straight away if you have any of these symptoms.
of these effects: Ear problems (ringing in the ears, changes in hearing and uncommonly high frequency hearing loss which may be permanent), numbness or tingling in	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.
hands and feet, (which may be temporary or permanent). Irritation and redness of the eye (rarely causing blurred vision with eye pain, sensitivity to light), headache, dehydration, pain or discomfort in bones, joints and muscles.	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 during treatment and for up to 12 months afterwards. Use effective contraception during this time. You can talk to your doctor or nurse about this.
 Changes in lung function (causing difficulty in breathing and/or cough), high uric acid levels (e.g. gout), constipation. Severe infusion related reactions with cetuximab (severe breathing difficulties, hives, fainting, chest pain). 	Complications of treatment can very 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

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Any other risks and information	
☐ I have discussed the intended benefit and risks of the alternative treatments (including no treatment).	e recommended treatment, and of any available
I have discussed the side effects of the recommender 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 effect I have discussed what the treatment is likely to invol of the treatment, blood and any additional tests, follow-	ve (including inpatient / outpatient treatment, timing
☐ I have explained to the patient, that they have the rig contact the responsible consultant or team if they wish	ght to stop this treatment at any time and should
I have discussed concerns of particular importance (please write details here):	to the patient in regard to treatment
Clinical management guideline/Protocol compl	liant (please tick):
Yes No Not available	
If No please document reason here:	
The following written information has	Health professional details:
been provided:	Signed:
☐ Information leaflet for cetuximab, carboplatin and fluorouracil	Date:
24 hour alert card or SACT advice service contact details	Name (PRINT):
SACT treatment record (cruk.org/treatment-record)	Job title:
Other, please state:	
Statement of interpreter (where appropriate propriate pr	
I have interpreted the information above to the patient they can understand.	to the best of my ability and in a way in which I believe
Signed: Date:	
Name (PRINT):	
Job title:	

Statement of patient

Patient identifier/label

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):

Date:

Name (PRINT):

Please read this form carefully. If your treatment has been planned in advance, you should already have your

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.



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 aidememoir 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 s).

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:

Patient identifier/label

- 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 Scotlish legal framework.

References

- Summary of Product Characteristics (SmPCs) for individual drugs: https://www.medicines.org.uk/emc
- Cancer Research UK: https://www.cancerresearchuk.org/aboutcancer/cancer-in-general/treatment/cancer-drugs
- Macmillan Cancer Support: https://www.macmillan.org.uk/ information-and-support/treating/chemotherapy/drugs-andcombination-regimens
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form