PATIENT AGREEMENT TO SYSTEMIC ANTI-CANCER THERAPY: Bevacizumab

NAME OF PROPOSED COURSE OF TREATMENT (include brief explanation if medical term not clear)

- Bevacizumab for the treatment of breast cancer.
- Given intravenously on day 1 every 14 or 21 days, until disease progression or unacceptable toxicity. Bevacizumab treatment is given in combination with chemotherapy - a separate consent form must be completed for the chemotherapy regimen.

WHERE THE TREATMENT WILL BE GIVEN:

- outpatient  
- day unit/case  
- inpatient  
- other:________________________

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust’s consent policy)

I have explained the procedure/treatment to the patient. In particular, I have explained:

✓ all relevant boxes

THE INTENDED BENEFITS

- CURATIVE – to give you the best possible chance of being cured.
- DISEASE CONTROL/PALLIATIVE – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival.
- ADJUVANT – therapy given after surgery to reduce the risk of the cancer coming back.
- NEO-ADJUVANT – therapy given before surgery/radiotherapy to shrink the cancer, allow radical treatment and reduce the risk of the cancer coming back.
STATEMENT OF HEALTH PROFESSIONAL

COMMON SIDE EFFECTS:
More than 10 in every 100 (>10%) people have one or more of the side effects listed:

- Tiredness and feeling weak (fatigue), high blood pressure, taste changes, poor appetite, feeling sick, diarrhoea and abdominal (tummy) pain, constipation, watery eyes, pain affecting the joints, muscles, chest or abdomen, and tingling in the fingers and toes.

- When bevacizumab is given in combination with chemotherapy there is 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 (99.5°F) or over 38°C (100.4°F), depending on the advice given by your chemotherapy team
- you suddenly feel unwell (even with a normal temperature)

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

- Infusion-related side effects, which are usually mild but rarely can be more severe. These include flu-like symptoms such as a headache, high temperature and chills, skin rash, oversensitivity/allergic reactions, feeling sick or being sick. You may notice these while the drug is given or sometimes a few hours after treatment. They are usually most noticeable with the first or second infusion, so these infusions may be given more slowly.

- Nose bleeds, protein in the urine, heart problems, increased risk of bleeding, dry or sore mouth, a hoarse voice or difficulty speaking, headaches, a runny nose, dry skin and skin changes, sleepiness, and a faster heart rate.

OTHER RISKS:

- A rare but potentially serious side-effect is gastrointestinal perforation and fistula. Contact your doctor if you experience sudden intense abdominal (tummy) pain.
- Very rare cases of reversible leukoencephalopathy with seizures, headache, altered mental status and visual disturbances have been described.
- A rare but serious risk of developing jaw problems (osteonecrosis) most commonly in patients who have previously received or are receiving IV bisphosphonates; a dental examination and appropriate preventive dentistry should be considered prior to starting treatment with bevacizumab.
- 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 while you are having treatment and for at least 6 months afterwards. It is important to use effective contraception during and for at least 6 months after treatment. You can talk to your doctor or nurse about this.
- Very 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.
STATEMENT OF HEALTH PROFESSIONAL (continued)

ANY OTHER RISKS:

☐ 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 discussed the intended benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

THE FOLLOWING LEAFLET/TAPE HAS BEEN PROVIDED:

☐ Information leaflets for bevacizumab.

☐ 24 hour chemotherapy service contact details

☐ Other, please state: ____________________________

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 s/he can understand.

Signed: ____________________________ Date: ____________________________

Name (PRINT): ____________________________

Job title: ____________________________
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 agree to the procedure and course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate training and experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion:

_________________________________________  ____________________________
Patient’s signature: Date:

Name (PRINT):

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

_________________________  ____________________________
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 with the patient that s/he has no further questions and wishes the procedure 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 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.

TO BE RETAINED IN PATIENT NOTES
Prepared by: Rena Chauhan
Checked by Pharmacist: Melanie Dalby
Checked by Consultant: Anne Rigg

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Approved by: Janine Mansi (National Chemotherapy Board)
Check www.cancerresearchuk.org for latest version
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) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:

• 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.

REFERENCES
1. Summary of Product Characteristics (SPCs) for individual drugs: https://www.medicines.org.uk/emc/
4. Guy’s and St. Thomas’ NHS Foundation Trust, Chemotherapy consent forms.