**PATIENT AGREEMENT TO SYSTEMIC THERAPY: CONSENT FORM BEVACIZUMAB**

**Hospital Name:**

- Guy’s Hospital
- St. Thomas’ Hospital
- King’s College Hospital
- Lewisham Hospital
- South London Healthcare NHS Trust:
  - Princess Royal University Hospital
  - Queen Elizabeth Hospital
  - Queen Mary’s Hospital

**Colorectal Unit**

Chemotherapy for Colorectal cancer – Intravenous Bevacizumab

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

- Bevacizumab intravenous
- Two Weekly
- Three weekly
- A separate consent form exists and must be completed for concomitant Chemotherapy, when relevant

**Statement of health professional** (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

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

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**To be retained in patient’s notes**

Reason for Update: CDF guidance

Version: 1

Supersedes: All other versions

Prepared by: Sanna Eestilä

Approved by SELCN DTAC Chair: Janine Mansi 02/12/2011

Review date: November 2013

Approved by Consultant: Nick Maisey

Date: 28/11/2011

Checked by: Nick Maisey

Date: 28/11/2011
The intended benefits

- Improved survival
- Control of symptoms
- Curative – to give you the best possible chance of being cured
- 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 recurrence of cancer
- Neo-adjuvant – therapy given before surgery to shrink the cancer and reduce the risk of recurrence of cancer

Significant, unavoidable or frequently occurring risks:

- Early side-effects include 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 will 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 are given more slowly.

- Other side-effects, which may occur a few days or weeks after treatment include diarrhoea or constipation, headaches and feeling sick (nausea), tiredness, high blood pressure, sore mouth and ulcers, loss of appetite.

- Increased risk of developing blood clot or bleeding problems and slow wound healing are associated with Bevacizumab therapy.

- Less common but potentially life threatening side-effects include reduced resistance to infection which can lead to a blood infection. Contact your doctor or the hospital straight away if:
  - your temperature goes above 38°C (100.4°F)
  - you suddenly feel unwell (even with a normal temperature)

- Rare but potentially serious side-effect is gastro-intestinal perforation. Contact your doctor if you experience gastric pain or discomfort.

- Rare side-effects include heart problems, effect on renal function and tumour pain.

- Bevacizumab may damage the cellular or genetic development of a foetus, leading to the many risks associated with an abnormal pregnancy. Therefore, I have discussed the issues of protected sex. This is an issue for both men and women.

- What the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, follow-up appointments etc) and location.

Any other risks:
I have also discussed what the procedure is likely to involve, the 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:

☐ Cancerbackup leaflet for Bevacizumab
☐ 24 hour chemotherapy service contact details

Signed:…………………………………… Date .. ..........................
Name (PRINT) .......................... ........... Job title .................

Contact details (if patient wishes to discuss options later) ........................................

Statement of interpreter (where appropriate)

Language Line ref:..............................................................

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) .................................................................

Copy accepted by patient: yes/no (please ring)
Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 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. 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Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for

This form documents the patient’s agreement to go ahead with the investigation or 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, however, 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 Department of Health’s Reference guide to consent for examination or treatment for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

Who can give consent

Everyone aged 16 or more 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 he or she will have the capacity to give consent for himself or herself. Young people aged 16 and 17, and legally ‘competent’ younger children, 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 for himself or herself, some-one with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, 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 mental 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 form 4 (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 that information as part of the 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 so under a Lasting Power of Attorney or as a court appointed 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 ‘serious 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 page 2 of the form or in the patient's notes.

References:
1- South East London Cancer Network, Agreed lists of Chemotherapy Regimens  
   http://www.selcn.nhs.uk/portal/index.asp
2- Macmillan Cancer Support, Cancer Information  
3- Royal Marsden NHS Foundation Trust, Consent Forms