



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Operations Office

Date: July 1, 2011

To: NCCTG Principle Investigators
NCCTG Primary Clinical Research Associates

From: Tamra Chomjak, MBA
Research Protocol Specialist III

Re: Requested tissue submission for N0775, A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV Malignant Melanoma

As a result of Addendum 12 for the above listed NCCTG study and the request for optional tissue collection, we have developed 2 letters for use for contacting patients and/or patient relatives to request consent.

Please note that these letters will be distributed to the NCCTG memberships on July 1, 2011. You may download the protocol material by clicking on the link below:

http://ncctg.mayo.edu/protocols/N0775/TissueRequestLetters_ProtMail_01Jul2011.pdf.

If you have trouble accessing this document, please feel free to contact me.

Thank you.



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IRB# (Insert Number)

Principal Investigator: (Insert name of treating physician).

Date:

*{ Name}
{ Street Address}
{ City, State Zip}*

RE: *{ first name} { last name}*
Patient ID# *(If applicable):*

You were involved in a research study about melanoma. We are asking for your permission to use your tumor tissue sample. The tissue sample was collected prior to your study treatment and kept in a tumor tissue registry as part of normal clinical procedures through the North Central Cancer Treatment Group (NCCTG). The testing performed on the tissue sample will be done in order to understand how your cancer responded to the treatment. It is hoped that this will help investigators better understand melanoma.

There are no known risks to you from taking part in this optional research study. You will not be required to attend any appointments at **(Insert name of treating institution)** for the purpose of this research.

You will not receive any direct benefit from participating in this part of the study. It is for the benefit of research. The information learned may help other patients with these diseases in the future.

You will receive no payment for your participation.

Any information you provide will be kept confidential by a code given to your tissue sample secured in a locked database. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

Please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time. Specifically, your current or future medical care at **(Insert name of treating institution)** will not be jeopardized if you choose not to participate.

If you have any questions about this research study you can contact **(Insert Treating Physician name), M.D. (XXX) XXX-XXXX)**. If you have any concerns, complaints, or general questions about research or your rights as a participant, please contact the **Insert your IRB name)** Institutional Review Board (IRB) to speak to someone independent of the research team at **(XXX) XXX-XXXX)** or toll free (if applicable) at **(XXX) XXX-XXXX)**.

Sincerely,

(Insert Treating Physician name), M.D.
(Insert appropriate mailing address)

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IRB #

Principal Investigator: **(Insert Treating Physician name)**

RE: *{ first name}{ last name}*

Patient ID # *(If applicable):*

I do **not** wish to participate in this optional tissue study.

I **would** like to give permission for use of my tissue sample for melanoma research and have read and signed the attached consent form.

I would like more information about this optional research study before I make my decision. Please call me.

(Please complete the contact information below).

Your name: _____

Telephone number: (____) ____ - _____

(____) ____ - _____

Today's date: ____/____/____

Best time to call: Morning Afternoon Evening

Best day(s) to call: _____

Thank you!



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IRB# (Insert Number)

Principal Investigator: (Insert name of treating physician).

(Date)

*{ Name }
{ Street Address }
{ City, State Zip }*

RE: *{ first name } { last name }*
Patient ID# *(If applicable):*

Dear *{ Mr., Ms, or Mrs. }*

Your relative, _____, was involved in a research study about melanoma. We are asking for your permission for use of his/her tumor tissue sample. The tissue sample was collected prior to study treatment and kept in a tumor tissue registry as part of normal clinical procedures through the North Central Cancer Treatment Group (NCCTG). The testing performed on the tissue sample will be done in order to understand how the cancer responded to treatment. It is hoped that this will help investigators better understand melanoma.

Please understand your permission is voluntary. Specifically, your current or future medical care at **(Insert name of treating institution)** will not be jeopardized if you choose not to give permission.

If you have any questions about this research study, please contact your **(Insert Treating Physician name), M.D.** at 1 **(XXX) XXX-XXXX**. If you have any concerns, complaints, or general questions about research or your rights, please contact the **(Insert your IRB name)** Institutional Review Board (IRB) to speak to someone independent of the research team at **(XXX) XXX-XXXX** or toll free (if applicable) at **(XXX) XXX-XXXX**.

If you do not wish to give permission, please indicate on the next page and return this letter since it will make a follow-up telephone call unnecessary. Thank you very much for your time and consideration.

Sincerely,

(Insert Treating Physician name), M.D.
(Insert appropriate mailing address)

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IRB #

Principal Investigator: **(Insert Treating Physician name)**

RE: *{ first name}{ last name}*

Patient ID # *(If applicable):*

I do **not** wish to give permission for use of my relative's, *(name)*, tissue sample for melanoma research.

I **would** like to give permission of my relative's, *(name)*, tissue sample for melanoma research and have read and signed the attached consent form.

I would like more information about this research study before I make my decision. Please call me. *(Please complete the contact information below).*

Your name: _____

Telephone number: (____) ____ - _____

(____) ____ - _____

Today's date: ____/____/____

Best time to call: Morning Afternoon Evening

Best day(s) to call: _____

Thank you!