Clinical Trial: GI005-Addendum

This is a cover page for a consent form for a clinical trial. This cover page provides the contact information for your physician and research staff.

This consent form contains important information to help you decide whether to participate in this clinical trial. Your physician and research staff will explain this trial to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- Being in a clinical trial is voluntary – your choice.
- If you join this clinical, you can still stop at any time.
- No one can promise that a clinical trial will help you.
- Do not join this clinical trial unless all of your questions are answered.

After reading and discussing the information in this consent form you should know:

- Why this clinical trial is being done;
- What will happen during the clinical trial;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this clinical trial;
- How your personal health information will be treated during the clinical trial and after the trial is over;
- Whether being in this clinical trial could involve any cost to you; and
- What to do if you have problems or questions about this clinical trial.

Some of the hospitals that are members of Montana Cancer Consortium are Catholic health institutions and therefore uphold the Ethical and Religious Directives for Catholic Health Care Services that do not promote or condone artificial/ medically induced pregnancy prevention methods. The attached consent may contain language that is not consistent with this religious directive.

Please read this consent form carefully.

You should talk to your doctor or research coordinator about any questions or concerns you have about this study. Their contact information is listed below.

Physician Name & Phone Number:

Research Coordinator Name & Phone Number: _____

Cancer Center Address: _____

You may also contact Montana Cancer Consortium
2132 Broadwater Ave, Suite A1, Billings, MT 59102
Phone: 406-969-6060, Fax: 406-969-6070

Acknowledgement of Consent Cover Page

_____

Participant Signature Date

NRG ONCOLOGY SAMPLE CONSENT FORM ADDENDUM 1

Study Title for Participants: Using cancer cells in the blood (ctDNA) to predict if chemotherapy will benefit patients who have had surgery for early stage colon cancer.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
NRG-GI005: Phase II/III study of Circulating tumOr DNA as a predictive BiomaRker in Adjuvant chemotherapy in stage IIA colon cancer (COBRA) (NCT #04068103)

When you joined the NRG-GI005 study, the group conducting the trial promised to tell you about new information that might affect your participation in the trial. There has been a change made from the time you signed the original consent form.

Commercial test available outside study to test for ctDNA

In the past, testing for ctDNA was not done for early stage colon cancer patients who are considered to be at low-risk for cancer returning. Commercially available test(s) for ctDNA are now available outside of this study. There is no test (including ctDNA) that exists that helps doctors identify with certainty which patients with early stage colon cancer do or do not benefit from chemotherapy. Use of ctDNA tests are not considered to be standard-of-care at this time, but are commercially available. It is not known yet how these tests should be used in making treatment recommendations for patients with your type of cancer, or if making decisions in treatment for patients with stage II colon cancer based on the ctDNA results will lead to longer survival.

Who can answer my questions about this study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact information for your study doctor is listed on the consent cover page. You may withdraw from this study at any time, and it will not affect your future care.

Signatures

I have been given this new information that was not in the original consent form. I have been given a signed and dated copy of this consent form addendum.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)

Consent Acknowledgement Form

By signing this form I, _____ am acknowledging the following:

- I have been given adequate time to review the consent form for Clinical Trial GI005.
- My physician has answered my questions to my satisfaction at this point.
- If I have any study-related questions in the future, I will talk with my doctor, nurse, or research coordinator.
- I understand that participation in this clinical trial is optional, and that I may withdraw from the trial at any time.
- No matter what I decide to do, and whether or not I decide to participate in this study, my decision will not harm the care that I receive or my relationship with my doctor, nurses, or other healthcare provider.
- No study procedures specific for this clinical trial were performed prior to my signing this consent form.
- I have reviewed with my doctor all medications that I am currently taking, including nonprescription medications, vitamins, herbal supplements, and naturopathic preparations, to avoid possible drug interactions.
- I have been informed of the potential reproductive risks associated with treatment on this clinical trial and understand precautions must be taken to avoid pregnancy while undergoing treatment and for a period of time after the conclusion of treatment.
- While abstinence is the most effective way of preventing a pregnancy, we understand that you may consider other pregnancy prevention methods. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention methods.
- If I become pregnant or have reason to believe I might be pregnant or fathered a child while receiving treatment on this clinical trial, I will notify my doctor immediately.
- Once I am no longer receiving treatment on this clinical trial, I may discuss with my doctor when it may be safe to become pregnant or father a child.
- I have received a signed copy of the consent form for the above named clinical trial.

_____ _____
Patient Signature Date

_____ _____
Person Obtaining Consent Signature Date

Montana Cancer Consortium
Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The NRG, is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a NRG research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number, medical record number, initials, and date of birth.

You may request a blank copy of the NRG data forms from Montana Cancer Consortium to learn what information will be shared.

3. Why do the researchers want my personal health information?

Montana Cancer Consortium will collect your health information and share it with NRG if you enter a cooperative group research study, or to evaluate your eligibility for a study. NRG will use your information in the following cancer research study:

NRG GI005: Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)

4. Who will be able to use my personal health information?

Montana Cancer Consortium will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. Montana Cancer Consortium may also permit the following groups to come in to review your original records that are kept by Montana Cancer Consortium so that they can monitor their research study**:**

- National Cancer Institute (NCI) Central Institutional Review Board (CIRB)
- the NRG Operations Center;
- the NRG Biostatistical Center;
- the Cancer Trials Support Unit (CTSU) or designees, a research group sponsored by the National Cancer Institute to provide greater access to cancer studies;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with NRG research efforts. This may include drug manufacturers, drug companies that may provide partial support for the study, drug distributors, and/or their designees; and
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the bullets above.

5. How will information about me be kept private?

NRG will keep all patient information private to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. NRG will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the institution below. They will make sure your written request to withdraw your permission is processed correctly.

Montana Cancer Consortium
2132 Broadwater Ave, Suite A1
Billings, MT 59102
406-969-6060
Fax: 406-969-6070

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by Montana Cancer Consortium. You do not have the right to review and/or copy records kept by NRG or other researchers associated with the research study.

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Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient: _____Date: _____

Signature of Person Obtaining Permission: _____Date: _____

Printed Name of Person Obtaining Permission: _____