Title of this Registry
Integrated Cancer Repository for Cancer Research (iCaRe²)

Invitation
You are invited to take part in this registry/tissue bank. You have a copy of the following, which is meant to help you decide whether or not to take part:
- Informed consent form
- "What Do I Need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Why are you being asked to be in this registry?
You are asked to participate because you have been diagnosed with cancer or you may have an increased risk for developing cancer.

What is the reason for doing this registry?
This registry/tissue bank is focused on the collection of detailed information and biological samples on participants to help create a resource that will be helpful to cancer researchers to study risk factors for a number of different types of cancer and other diseases which relate to cancer. It is our hope that future research using information from this registry/tissue bank will lead to improved diagnosis, prevention and treatment of all cancers.

What will be done during this registry?
You will be asked to:
1. Complete a survey about yourself, your medical history, diet and lifestyle habits, environmental exposures and family history. The survey should take up to an hour to complete. You may be asked to complete follow-up surveys at numerous time points while you are being treated at UNMC.

2. Allow us to contact you for additional information or clarification of the information you provided in the completed forms by telephone at a time(s) that is best for you.

3. Allow us to collect information from your medical record. You may be asked to give us permission to contact your doctor for more information about your medical history, which may include results of genetic testing done as part of routine clinical care.

4. Donate no more than 3 tablespoons of blood at enrollment or as close to...
enrollment as possible and allow us to obtain a portion of biopsied tissue which was/will be collected and saved from your surgery or biopsy. If necessary we may ask you to provide additional blood samples no more than twice a year. This amount will not exceed 3 tablespoons. If you develop cancer or if your cancer recurs, we will ask you to donate no more than 3 tablespoons of blood when you come to see your doctor.

5. You may be asked to provide a few urine samples (about 1/4 cup each time) at various follow up visits.

6. Allow authorized personnel to contact you in the future for reasons such as to obtain consent for additional uses of your stored medical history information and/or biological samples, to obtain updated or additional information, or to contact you to participate in other research projects.

7. Your samples may be used by researchers in future research studies which may include studies on your genes and/or to establish a cell line (a group of identical cells that are grown from a cell from your sample) done at University of Nebraska Medical Center/The Nebraska Medical Center (UNMC/TNMC), at collaborating academic institutions or at outside commercial (for profit) entities.

Every human being is made up of genes that we inherit from our parents. Genes determine our physical traits like hair and eye color. Genomic sequencing tests give investigators your entire genetic makeup. Since each person has a unique genetic makeup, it is possible (although unlikely) to identify a person through the results of genetic tests being performed in this study. The Investigators will not keep any identifying information associated with your results, however it is still possible a loss of confidentiality to occur.

8. You may be asked to sign a Release of Information. This form is to allow us to contact your doctor for additional information such as outside records, retrieving tissue slides when you are being treated elsewhere.

What are the possible risks of being in this registry?
Blood drawing: You may experience a slight discomfort when the needle is inserted. There may also be a small amount of bleeding or bruising at the site where the needle is inserted. There is a small chance that you could get an infection or clot in the vein when blood is drawn.

Breach of Confidentiality: Every attempt will be made to keep the information you
give us about you and your family confidential. However, it is possible that other people could discover this information. Upon enrolling into this registry, you will be provided with a unique case number. Prior to submission of any data in the cancer registry, any private information about you will be encrypted and protected by limited access capability and password protection for authorized users only.

Psychosocial: You may find talking about cancer distressing. If at any time there would be a question on the survey that you are uncomfortable answering for any reason, you are not required to do so.

Taking part in this registry/tissue bank could have unexpected risks that are not known at the present time.

What are the possible benefits to you?  
You are not expected to get any benefit from being in this registry/tissue bank.

What are the possible benefits to other people?  
The information and specimens gathered from this registry/tissue bank may help researchers gain a better understanding of cancer, determine risk factors, advance treatment and discovery of prognostic markers. This registry/tissue bank may help identify those who might benefit from screening measures for early detection which may lead to more options for treatment.

What are the alternatives to being in this registry?  
Instead of being in this registry/tissue bank you can choose not to participate.

What will being in this registry cost you?  
There is no cost to you to be in this registry/tissue bank.

Will you be paid for being in this registry?  
You will not be paid to be in this registry/tissue bank.

In the event that any commercial products are developed from your donated biological samples (i.e. blood, urine and tissue), there are no plans to share any revenues with you from those commercial products. It is policy that all donated tissue is the property of the Organization.

Who is paying for this registry?  
This registry/tissue bank is being paid for by grant funds from Fred and Pamela Buffett Cancer Center’s Philanthropic fund, National Institutes of Health (NIH),

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What should you do if you have a problem during this registry?
Your welfare is the main concern of every member of the registry/tissue bank team. If you have a problem as a direct result of being in this registry/tissue bank, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
All necessary steps will be taken to protect the privacy and the confidentiality of your data.

You have rights regarding the protection and privacy of your medical information collected for this registry. This medical information is called "protected health information" (PHI). PHI used in this registry/tissue bank may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays, as well as the results of other diagnostic and medical procedures, as well as your medical history. Your data and medical records will be maintained in a secure manner.

The registry/tissue bank has obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate of Confidentiality is intended to protect only the confidentiality of the medical history and genetic test result data collected as part of this registry/tissue bank. It does not protect information from this registry/tissue bank required for audit or program evaluation by the U.S. Department of Health and Human Services, requested by the Food and Drug Administration, placed in a health care provider’s medical records. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The researchers will not voluntarily disclose, without your consent, information that would identify you as a participant in this research project.

The protection afforded by the Certificate of Confidentiality is permanent and remains

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in effect after death of the registry participant. It does not represent an endorsement of the Department of Health and Human Services.

Who will have access to information about you?
By signing this consent form, you are allowing the investigators listed on the consent form to have access to your PHI. The registry/tissue bank team includes the investigators listed on this consent form and other personnel involved in this specific registry/tissue bank at the Institution.

Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this registry?"

You are also allowing the registry/tissue bank team to share your PHI, as necessary, with other people or groups listed below:
- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Investigators involved in this registry/tissue bank
- Internal and external investigators not currently identified
- Federal law requires that your information may be shared with these groups:
  - The HHS Office of Human Research Protections (OHRP)
  - The Food and Drug Administration (FDA)
  - National Institutes of Health (NIH)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
  - The Fred and Pamela Buffett Cancer Center Scientific Review Committee (SRC)

You are authorizing us to use and disclose your PHI for as long as the registry/tissue bank is being conducted.

You may cancel your authorization for further collection of PHI for use in this registry/tissue bank at any time by contacting the principal investigator in writing. However, the PHI which is included in the registry data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this registry/tissue bank.

What will happen if you decide not to be in this registry?
You can decide not to be in this registry/tissue bank. Deciding not to be in this registry will not affect your medical care or your relationship with the investigator or the Institution. Your doctor will still take care of you.

You will not lose any benefits to which you are entitled.

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What will happen if you decide to stop participating once you start?
You can stop participating in this registry/tissue bank ("withdraw") at any time. Should you wish to stop participating in the registry/tissue bank, please contact one of these individuals in writing requesting that your data no longer be used for future research purposes:

Whitney Goldner, 984120 Nebraska Medical Center, Omaha, NE 68198-4120; Alice Kueh, 986805 Nebraska Medical Center, Omaha, NE 68198-6805

Deciding to withdraw will not otherwise affect your care or your relationship with the registry/tissue bank team or this institution. You will not lose any benefits to which you are entitled.

When leaving the registry/tissue bank, please note that the stored samples and corresponding data will be destroyed upon request but that any tissue and data that has been used in research studies up to that point will continued to be used.

Please note we are unable to withdraw any data that are kept without identifiers.

Will you be given any important information during the registry?
If the registry/tissue bank team gets any new information during this registry/tissue bank that may affect whether you would want to continue being in the registry, you will be informed promptly.

What should you do if you have any questions about the registry?
You have been given a copy of "What Do I Need to Know Before Being in a Research Study?" If you have any questions at any time about this registry/tissue bank, you should contact the Principal Investigator or any of the registry personnel listed on this consent form or any other documents that you have been given.

What are your rights as a registry participant?
You have rights as a registry/tissue bank participant. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights or complaints about the registry, you can contact any of the following:
- The investigator or other registry personnel
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463.
  - Email: IRBORA@unmc.edu

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MARKING YOUR CHOICE:
Please read each sentence below and think about your choice. After reading each sentence, check “Yes” or “No” and initial your choice.

1. You agree to fill out the questionnaires about yourself. We may ask you to fill out follow-up surveys at numerous time points while you are being treated at UNMC.
   Yes [___] No [___] Initials________

2. You agree to donate a blood sample to be stored at UNMC for use in future studies done here or at collaborating institutions. If necessary we may ask you to provide additional blood samples no more than twice a year.
   Yes [___] No [___] Initials________

3. You agree to donate urine samples to be stored at UNMC for use in future studies done here or at collaborating institutions. You may be asked to provide a few urine samples (about 1/4 cup each time) at various follow up visits.
   Yes [___] No [___] Not applicable [___] Initials________

4. You agree to release a portion of biopsied tissue collected and saved from surgery or biopsy (done in the past or future) for tissue banking for use in future studies done here or at collaborating institutions.
   Yes [___] No [___] Not applicable [___] Initials________

5. You agree to allow authorized personnel from the registry/tissue bank at UNMC to contact you in the future to obtain consent for additional uses of your stored information and biological samples, to obtain updated or additional information, or to contact you to participate in other research projects.
   Yes [___] No [___] Initials________

6. You agree to share your banked data, blood and/or tissue for future studies done at a commercial company.
   Yes [___] No [___] Initials________

You are freely making a decision whether to participate in the registry/tissue bank.

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Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects.
- You have had your questions answered.
- You have decided to participate in the registry.
- If you have any questions, you have been directed to talk to one of the individuals listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Participant __________________________
Date _______________

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant, and all of their questions have been answered. In my judgment, the participant possesses the capacity to give informed consent to participate in this registry/tissue bank and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent __________________________
Date _______________

Authorized Registry Personnel
Principal
Goldner, Whitney
phone: 402-559-6876
degree: MD

Participating Personnel
Are, Chandrakanth
phone: 402-559-8941
degree: MD

Enke, Charles Arthur
phone: 402-552-3844
degree: M.D.

Ganti, Apar Kishor K
phone: 402-559-8121
degree: MD

Grem, Jean Linette
phone: 402-559-3233
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LaGrange, Chad Allen
phone: 402-559-4292
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Lackner, Rudy Paul
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phone: 402-559-7775
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phone: 402-559-8076
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phone: 402-552-3844
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phone: 402-559-4726  
degree: RN

Mailliard, Mary J  
phone: 402-559-5582  
degree: RN

Meisinger, Rose  
phone: 402-559-3944  
degree: RN

Newcomb, Jefferey (Jeff) Allen  
phone: 402-559-6277  
degree: BS

Pracht, Shelby  
phone: 402-559-9116  
degree: NA

Pufall, Janine D  
phone: 402-559-7272  
degree: BS

Radniecki, Sarah E  
phone: 402-559-8197  
degree: RN

Selzle, Jill Renee  
phone: 402-559-4389  
degree: PA-C, MPAS

Severson, Megan Christine  
phone: 402-559-5082  
degree: BS

Treude, Kelly J  
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Urban, Terrie Lois  
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IRB
Approved 06/04/2014
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