CONSENT FORM

Wilmot Biobank Pan-Cancer Biospecimen and Data Collection

Principal Investigator: Bradley N. Mills, Ph.D.

This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family and/or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time. If you choose not to participate, your routine medical care will not be changed in any way.
- You are being asked to take part in this study because of one of the following:
  - (i) You will be having a biopsy or surgery for a cancerous, potentially cancerous, or otherwise diseased organ.
  - (ii) You will be having a non-surgical treatment (e.g., chemotherapy, radiation) for a cancerous, potentially cancerous, or otherwise diseased organ.
  - (iii) You will be undergoing screening for cancer (e.g., colonoscopy, mammography).
- The purpose of this study is to collect cancerous, potentially cancerous, and/or non-cancerous 'control' tissues, as well as blood and/or urine for research purposes.
- Participation in this study will not impact patient care in any way and there are no health risks associated with participation.
- Your tissue samples and clinical information will be stored for an indefinite period.
- You will not benefit from being in this study.
- There are risks from participating in this study, the most common being a potential for invasion of privacy or breach of confidentiality. See the *"Risks of Participation"* section in this consent form for more information. You should discuss these risks in detail with the study team.

Purpose of Study

The purpose of this study is to improve and accelerate cancer research through the establishment of the Wilmot Biobank at the University of Rochester Medical Center (URMC). This state-of-the-art biobank will collect and store human tissue and fluid samples (that would otherwise be discarded) as well as clinical information to provide current and future URMC researchers with the resources they need to develop new preventative, diagnostic, and therapeutic tools.

Description of Study Procedures

If you decide to take part in this study, you will be asked to donate leftover tissue (from your biopsy/surgery), blood, and/or urine for future research. Normally these tissues/fluids are thrown away but, with your permission, we will "bank" (store) them. When you go in for your surgery, non-surgical treatment, or cancer screening, a study team member, with help from the surgical team, pathologists, and/or venipuncture specialists, will obtain:

- If you are undergoing surgery – *tissue, blood, and/or urine*.
  Tissue samples removed by your surgeon during your surgery will be collected and no extra tissue will be removed for this study. Up to 50 ml (less than 4 tablespoons) of blood (from a blood vessel) and/or urine will be collected during your procedure. If you already have an intravenous (IV) line in place for your surgery, you will not have any additional needle sticks to obtain this blood. Urine will only be collected if you have had a bladder catheter inserted for surgery. In some instances, blood will be collected both at the time of surgery and post-surgery (1-12 weeks) because it is useful to compare biological markers between these time points. If you are selected for both collections, you will be informed during your consent before you agree to participate. The combined total amount of blood collected both before and after surgery will not exceed 50 ml.
- If you are undergoing a non-surgical treatment or screening – *blood only*.
  Up to 20 ml (less than 2 tablespoons) of blood from a blood vessel will be collected. If you already have an IV line in place for your treatment, you will not have any additional needle sticks to obtain this blood. In some instances, blood will be collected both at the time of treatment and post-treatment (1-12 weeks) because it is useful to compare biological markers between these time points. If you are selected for both collections, you will be informed during your consent before you agree to participate. The combined total amount of blood collected both before and after treatment will not exceed 50 ml.

The tissue removed during your surgery will be sent to the URMC Surgical Pathology laboratories, and any *extra tissue that is not needed by the pathologist for your clinical diagnosis and/or treatment will be given to the study team* for preservation and storage. If the pathologist decides that more analysis is required for clinical purposes, they can access the stored tissue from the Biobank as needed. Additionally, if there is enough extra tissue, some may be stored in a special tissue-preserving media as a "fresh" tissue collection. Fresh tissue collection is not a routine procedure and will only happen if there is a specific request made by researchers. The blood that was collected from you will be used for the preparation of serum, plasma, and blood cells. All blood and urine samples will be preserved and stored in the Biobank as well.

Clinical information (data) from your medical records and/or hospital reports will be collected. These data may include your age, race/ethnicity, diagnosis, medical history, medical treatment(s), and/or response to treatment(s). It will not include your name, social security number, or other information that could identify you. We will continue to review your medical record and collect follow-up information about your health status and treatment for up to 10 years after your enrollment. Your biological samples and clinical data that are stored in the Biobank will have all of your personal identifying information removed and will be labeled with a code. Only the Principal Investigator of this study will have the information that matches the code to you. Information documenting your study participation and a copy of your signed consent form will be included in your electronic health record. If you have concerns about this or would like to obtain more details, you should discuss this with the study team. All banked tissue, fluids, blood, and/or clinical data will be stored indefinitely in the Wilmot Biobank and managed by the Principal Investigator and their study team.

The tissue that is banked will only be used for research at URMC to learn more about the natural history, causes, diagnosis, and treatment of cancer. To get your data and/or biosamples, future researchers must seek approval from an internal scientific committee that will review and approve the proposed research projects before any samples or data are released. Your name and identifying information will be removed from any materials you provide before they are shared with other researchers so that researchers cannot easily identify you. The researchers will not have access to your medical records. If more clinical information about you is needed for future-use studies, we may share additional medical record data with researchers, but only if they provide evidence of Institutional Review Board (IRB) approval to access such information. Multiple URMC researchers may perform various types of research on your samples. For example, future research may involve looking at levels of certain markers to see how they may predict responses to a certain drug. No research results generated from your data and/or biosamples will be

returned to you. After research testing is complete, a sample has reached the end of its useful life and will be destroyed.

Your tissue, fluids, blood, and/or data may also be used for cancer studies that include researching your "genome". Your genome includes your genes, known as DNA (deoxyribonucleic acid), as well as other factors such as RNA (ribonucleic acid) and proteins that contain information your body needs to function and make you who you are. Genomic studies, including genome-wide association studies (GWAS), look at genetic differences in the entire human genome (the complete set of human genes). Researchers will collect this information to better understand cancer by looking for genetic connections that:

- may increase the likelihood of getting a certain type of cancer
- may affect the progression of cancer
- may affect treatments (chemotherapy, radiation) that work for certain cancers in some people, but not in others.

The National Institutes of Health (NIH), which is funding many of these studies, requests that researchers share any genomic data they create with other researchers. This is known as Genomic Data Sharing and means that your genomic data will be publicly available. This information will be stored and shared through an NIH open-access data repository. The repository includes all kinds of genomic data from various studies funded by the NIH. If a URMC investigator submits your genomic data, they will remove direct identifiers (such as your name) and assign a random code to your information before sending it to the repository. The NIH will never get this code or the identifiers that were removed. Anyone will be able to go to the website and download the information. We will not know what types of health-related research will be done with the data that are shared. If you would like more information about genomic research, open-access data sharing, or the various types of future-use research that your data and/or tissues may be used for, further details can be provided by the study team.

The decision to let us keep the leftover tissue is up to you. No matter what decision you make, it will not affect your care. If you decide now that your tissue can be used for future research, you can change your mind at any time. If you do change your mind, please contact Dr. Bradley Mills by phone at (585) 275-7272, or by email at Bradley_Mills@urmc.rochester.edu. Any of your tissue(s) that remains at that time will then be discarded, however, biosamples that have been already used, or any data that has been generated as a result of testing done on your sample will not be able to be retrieved or destroyed.

Number of Subjects

Approximately 10,000 subjects will take part in this study.

Risks of Participation

You should discuss the following risks in detail with the study team:

Tissue Donation: No extra tissue will be removed during your surgery simply because you are participating in this research study. No additional discomfort beyond what is associated with your normal surgical care will result from the collection of this tissue. If the hospital pathologist and/or surgeon decide that more tissue is needed for clinical analysis, they can access the tissue stored in the Wilmot Biobank as needed. Blood draws may cause pain, redness, bruising, or infection at the site of the needle stick. If possible, we will try to get the blood sample from a blood vessel line already inserted for your procedure so that you will not experience an extra needle stick.

Loss of Confidentiality: There is a potential for invasion of privacy or breach of confidentiality because this study involves collecting personal, identifiable information about you. To minimize this risk, we will assign you a study number code instead of labeling the information we collect from you with your name or medical record number. All of the information we collect will be stored securely and only study team members will have access to it. We will make every attempt to protect your confidentiality and make sure that your identity does not become known.

The study team may be notified if you receive other healthcare services at URMC or its Affiliates (e.g., visit the emergency room). In addition, the following individuals may know you participated in the research and may see the results of testing conducted for this study:

- Staff at the URMC and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Healthcare providers who are involved in your care at a facility that is not part of the URMC and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Genomic Research: It is possible that someday in the future your tissue could be linked back to you just based on your genes because the genetic information in your tissue is unique to you. This risk is higher for individuals with rare diseases or from specific minority populations. We will remove your name and any other identifying information that could directly identify you from your sample and replace it with a subject number code. All other study information will be stored securely and only study personnel will have access to this information. There may also be risks to your privacy and/or the privacy of your relatives from storing and sharing your information in an open-access repository. Although the NIH takes measures to protect your privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information. We believe the chance that this will happen is very small, but we cannot make guarantees. If your genetic information were re-identified, personal information about you, your health, and your risk of disease could become known to others. This could present unknown risks. Your privacy and the confidentiality of your data are very important to us; we will make every effort to protect them.

Some genetic information can help predict future health problems for you and your family, and this information might be of interest to your employers or insurers. A federal law called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. To learn more about the GINA Law, please ask the study staff or check the internet.

Benefits of Participation

You will not benefit from being in this research study.

Costs

There will be no cost to you to participate in this study.

Payments

You will not be paid for participating in this study.

You will not receive any money that may result from any commercial tests or products that are developed as a result of this study.

Confidentiality of Records

The University of Rochester makes every effort to keep the information collected from you private. To do so, we will remove all of your personally identifying information and all of your data/biosamples will be labeled with a code. Only study team members will have the information that matches the code to you. Sometimes, however, researchers need to share information that may identify you with people that work for the University and/or regulators.

If you have never received a copy of the URMC and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institutes of Health

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last 10 years. Biosamples (tissue, blood, and urine) and clinical data will remain in the study indefinitely, or until they are used up or no longer useful for research.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

Future Use of Information/Samples

Your clinical information and biosamples might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your clinical information and/or biosamples are used or distributed.

Contact Persons

For more information concerning this research, or if you feel that your participation has resulted in any research-related injury, or emotional, or physical discomfort, please contact Dr. Bradley Mills at (585) 275-7272 or Bradley_Mills@urmc.rochester.edu.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- If the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free to not take part or withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefits to which you are entitled. If you do withdraw from this study, the information you have already provided will be kept confidential.

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

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date