

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Advanced Treatments for Adrenocortical Cancer: Adrenocortical Cancer Biospecimen Repository

PROTOCOL NO: Mdemeure 05-027
WIRB® Protocol #20051769

SPONSOR: Translational Genomics Research Institute
Phoenix, Arizona
United States

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**STUDY RELATED
PHONE NUMBER(S):** Michael J. Demeure, M.D., F.A.C.S.
520-694-5868 (24-hour)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

This is a clinical trial (a type of research study). Clinical studies include only subjects who choose to take part. Please take your time to make your decision. Please take time to talk with your doctors, hospital or other medical personnel, your family and friends, or anyone else. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You are being asked to take part in this study because you have adrenocortical cancer and will be undergoing surgery to remove the tumor.

Why Is This Study Being Done?

The objective of this study is to analyze the genetic (DNA) changes in adrenocortical tumors or blood from people with adrenocortical cancer, in order to allow researchers to try to develop new treatments for adrenocortical cancer.

These blood samples and tumors will be analyzed using a variety of laboratory tests. It is hoped that specific genes from the specimens may be targets for existing or new drugs used to treat adrenocortical cancer. However, this would need to be proved by further studies in people with the disease. Tumor tissue that is left-over and not needed for the laboratory testing will be stored in a biospecimen repository for potential future studies.

What is A Biospecimen Repository?

A biospecimen repository is a collection of blood or tissue samples from the human body and medical information about the persons who provided the samples. TGen is participating in a biospecimen repository that qualified researchers could use for future studies on adrenocortical cancer. The bank is operated by the Translational Genomics Research Institute (TGen) in Phoenix, Arizona and is headed by Dr. Michael Demeure.

About Using Specimens for Research

You will be undergoing or have undergone a surgical procedure to remove a tumor from your adrenal gland that is likely to be a cancer. You may be asked to participate in this study before or after your surgery if your tumor has been frozen. Residual tissue (tissue that would normally be removed from you by surgery and that would normally be destroyed) will be collected after the pathologist decides what tissue is needed for their usual tests. If you agree, this specimen will be kept and may be used in research to learn more about adrenocortical cancer.

In addition, we would like to collect about 10 ccs or 2 teaspoons of blood. The blood sample will be taken at the same time as a blood draw for your clinical care. You will not be "stuck" again to collect the blood sample for this study.

The research that will be done using your specimens probably will not help you. It might help people who have adrenocortical cancer in the future. Reports about the research done on your specimens may be given to your study doctor at your request. The research will not have an effect on your care.

Things to Think About

The choice to give blood and tissue for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimen can be kept for research, you can change your mind at any time. Just let us know that you do not want us to use your specimens. Then the specimen will no longer be used for research.

Part of your specimens will be used for genetic research (about diseases that are passed on in families). These results will not be put in your health records. Genetic research is the examination of genetic material by research scientists. Genetic testing will allow researchers to look for genetic changes in your samples that may one day be used in tests for identifying early stages of adrenocortical cancer. Genetic testing also lets researchers gain more knowledge about possible causes of adrenocortical cancer, which may one day help researchers find a treatment.

Your specimens will be used only for research. The research done with your specimens may help to develop new products in the future.

How Many Subjects Will Take Part in the Study?

Nationally, about 120 subjects will take part in this study.

What Is Involved in the Study?

If you give permission, portions of tumor tissue that are left over from your surgery will be stored in the TGen Biospecimens Repository along with your blood sample and related medical information (age, gender and tumor stage).

Your samples and medical information will be given a special code number, like a PIN, when they are sent to TGen. If possible, neither your name, address, date of birth or phone number will be sent to TGen with the sample.

It is possible that your name and treating physician contact information will be stored at TGen if you initiated participation in this study through the ATAC fund website. That information will be kept separate from your samples and only the TGen study coordinator will be able to link your sample to your information.

Only you, your study doctor, and your research nurse will know the connection between the special code number and your personal identifying information.

How Long Will I Be in the Study?

If you give permission, your samples and related medical information will be stored in the TGen Biospecimen Repository indefinitely. Your sample and related medical information may be made available to qualified researchers only for future research on adrenocortical cancer.

What Are the Risks of the Study?

The main risks are the possible loss of confidentiality and the risks associated with genetic testing.

Risk of a Breach of Confidentiality: There are risks associated with a loss of confidentiality of your health information and genetic testing results. Information about genetic test results may affect your employment, insurance, or family relationships. The sponsor cannot be certain that your genetic test results could never be linked to you.

Risks of Genetic Testing: Genetic testing sometimes reveals a previously unrecognized or unexpected genetic condition or problem. This condition may or may not affect your health. If possible and you give permission, such findings will be reported to you through your healthcare provider, who will explain the potential meaning of the finding. As a result of this knowledge, you and your family may experience stress, anxiety, or changes in your current way of life.

Are There Benefits to Taking Part in the Study?

We do not guarantee you will benefit if you take part in this study. We hope that it may someday help researchers better understand and provide better treatment for adrenocortical cancer.

What Are the Costs?

Participation in this study will not lead to any additional costs for you or your family.

Will I Get Paid?

You will not be paid for allowing your samples and medical information to be sent to the TGen Biospecimen Repository.

Are There Commercial Issues?

Your samples may someday be used for the development of new treatments or diagnostic methods which may be of commercial value to TGen. The TGen Biospecimen Repository has no plans to provide payment to you should this occur.

Are there Alternative Treatments?

Your alternative is to not be in this study.

What about Confidentiality?

Information from this study will be given to the sponsor. “Sponsor” includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). Research records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA;
- Department of Health and Human Services (DHHS) agencies;
- the Western Institutional Review Board[®] (WIRB[®]).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

The healthcare provider giving TGen your sample will sign a confidentiality statement agreeing not to give TGen any identifiable information about you. Should any breach of confidentiality occur, those sample(s) will be destroyed and discarded.

What if There Is a Breach of Confidentiality or I Am Harmed?

There are no plans to compensate you if there is a breach of confidentiality or you are hurt in any way as a result of participation in this biospecimen repository.

Who will Provide the Source of Fundings?

Funding for this research study will be provided by Translational Genomics Research Institute (TGen).

What Are My Rights as a Subject?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

What if There are New Findings?

We will tell you about important new information that might change your health, welfare, or decision to stay in this study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or a research-related injury, contact the study doctor, Michael J. Demeure, M.D. at or 520-694-5868 (24-hour).

If you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: ClientServices@wirb.com.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Decision to Participate in Research DNA Bank

You are making a decision as to whether or not to participate in the TGen Biospecimen Repository. Your signature will indicate that you have read the information provided above and have decided to participate. You may withdraw at any time after signing this consent form if you want to stop participating.

If you decide to participate, after careful thought, please indicate how you want to participate in the TGen Biospecimen Repository by selecting how you want your tissue and related medical information to be treated.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

(PLEASE INITIAL ONE CHOICE ONLY)

_____My samples and related medical information can be stored in the biospecimen repository and used for future research studies without contacting me to get permission. If possible, I would like to be informed through my healthcare provider if researchers identify something about me that could be important to my health or family planning.

or

_____My sample and related medical information can be stored in the TGen Biospecimen Repository and used for future research studies without contacting me to get permission. I do not want to be informed if researchers identify something about me that could be important to my health or family planning.

or

_____My sample and related medical information can be stored in the TGen Biospecimen Repository but I want to be contacted to give permission (consent) before it is used for future research.

or

_____My sample and related medical information can be stored in the biospecimen repository but I do not give permission (consent) for it to be used in future research.

Consent of Subject

I have read this informed consent form (or had it read to me). All my questions about the study and my participation in it have been answered. I voluntarily agree to participate in the TGen Biospecimen Repository, as indicated by my initials in the previous section of this consent form.

By signing this consent form, I have not given up any of my legal rights.

Print Name of Subject

Signature of Subject

Date

Signature of Person Conducting Informed Consent Discussion

Date

Statement of Person Obtaining Informed Consent

I have fully explained the Adrenocortical Cancer Biospecimens Repository to the above subject. I have discussed its purpose, its procedures, the possible risks and benefits, and the voluntary nature of participation. I have invited the subject to ask questions and have answered any questions that the subject has asked. I have given the subject a signed and dated copy of this consent form.

Signature of Person Obtaining Informed Consent

Date

----- Use the following only if applicable -----

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Signature of Impartial Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

Frequently Asked Questions about Specimens

What is a specimen and how is it used in research?

A specimen is typically a sample of blood, bone marrow, skin, toenails or other body materials. Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

What type of research will be done with my specimen?

Many kinds of research studies use specimens. Some researchers develop new tests to find diseases. Others find new ways to treat or even cure diseases. In the future, research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen will look for genetic causes and signs of disease.

How does TGen decide where my specimens are used?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They may contact TGen and request samples for their studies. TGen reviews the way these studies will be done and decides if any of the samples can be used. TGen gets the specimen and information about you from your healthcare provider (your doctor or hospital), and sends the specimen samples and de-identified information about you to the researcher. The researcher will never receive any identifiable information from TGen.

Will I find out the results of the research using my specimen?

You may receive the results of research done with your specimen if you consented to it with your initials, but this may take a long time because researchers must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and so may not affect your care right now, but the results may be helpful to people like you in the future.

Why do you need information from my health records with my specimen? Will you use my name?

To do research with your specimen, researchers may need to know some things about you. (For example: How old are you? Are you male or female?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to TGen. Your name, address, phone number and anything else that could identify you will be removed before they go to TGen. The researcher will not know who you are.

How will you make sure that I am not harmed after giving you my specimen?

Sometimes, health records have been used against patients and their families. For example, an insurance company may deny a patient insurance or an employer may not hire someone with a certain illness (such as cancer). The results of genetic research apply to you, and may apply to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members. TGen will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be removed from anything associated with your specimen before it is given to the researcher. This will make it very difficult for any research results to be linked to you or your family.

What if I have more questions?

If you have any questions, please talk to your study doctor or study nurse, or call WIRB®, our research review board at 1-800-562-4789 or 360-252-2500.