Consent for Use of Tissue and Health Records for Research

Study Title: {Title}

Study Doctor: {Investigator}

Study Site: Guthrie Medical Group, P.C.
One Guthrie Square
Sayre, PA 18840

Robert Packer Hospital
One Guthrie Square
Sayre, PA 18840

Telephone number: Guthrie Clinical Research 570-887-6072 or 1-800-836-0388

Key Information

You are being asked for your consent to take part in a research study.

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- Ask all the questions you want before you decide.

The purpose of this research is to study {describe purpose of the study in layman's terms}. Your participation will last {enter duration of participation}. The details of the study are described below.

This research is not part of your medical care. The research is voluntary. You do not have to take part if you do not want to. Your medical care will not be affected if you decide not to take part. If you decide not to take part, there will be no penalty to you, and you will not lose any of your regular benefits.

Using Your Tissue for Research

You are going to have a surgery to {…}. It is standard practice to examine part of the removed tissue in a hospital laboratory and discard whatever is leftover.

We would like to use the leftover tissue to conduct research to learn more about {…}. If you agree, the leftover tissue will be sent to {…}. The tissue will be used to study changes in gene expression and protein metabolism that may be involved in {…}. The tissue may be transferred to the Guthrie Foundation for research processing. Tissue samples will not have your name or any identifying information. Any tissue remaining after the studies are completed will be discarded. The research will not involve whole genome sequencing. There is a small possibility that the biospecimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

About {anticipated number} people will take part in this study.

Donald Guthrie Foundation is providing financial support for this study.

The research will not affect your care. Results of the research will not be given to you or your doctor, and reports of research using your tissue will not be put in your health record.
The choice to let us use the left over tissue for research is up to you.

Genetic Testing

[If genetic testing results will be returned to the site and/or the subject, include information about the Genetic Information Nondiscrimination Act (GINA)] 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. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.
Be aware that this Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Using Information in Your Medical Record

We would like to use information in your medical record to make our laboratory findings more useful. Information from your medical record will include your name, medical record number, age, gender, race, body mass index, dates of service and diagnoses for medical conditions related to the subject of the research.

Risks

The greatest risk to you is the release of information from your medical records. The Guthrie Clinic will protect your records so that your identifying information will be kept confidential. The chance that this information will be disclosed is very small.

Benefits

The benefits of research using tissue and medical records include learning more about diseases and how to treat them. There will be no direct benefit to you.

Alternatives

You do not have to participate in this study. Your study doctor can discuss with you the risks and benefits of alternatives.

Confidentiality

Your private information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. (OR - Your identifiable private information or biospecimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.)

Representatives from the Institutional Review Board of The Guthrie Clinic (a group of people who review the research to protect the rights of participants), Study Site Administration and federal regulatory agencies like the US Food and Drug Administration (FDA) may inspect research records that could reveal your identity. These persons are bound by confidentiality regulations. Information about you will be treated in strict confidence to the extent required by law.

Costs
There are no costs for taking part in this study. You or your insurance provider will be charged in the standard manner for any services that are part of routine care.

Research-Related Injury
If you are hurt or injured from being in the study, The Guthrie Clinic has no program to pay you or provide you with any other compensation for the injury. Medical care at The Guthrie Clinic is open to you as it is to all sick or injured people.

You do not give up any of your legal rights by signing this form.

Withdrawal
If you enter the study and then change your mind, you will be free to leave the study. The study doctor may stop you from taking part in this study at any time if he or she believes it is in your best interest or if the study is stopped. Your study doctor will discuss procedures for ending the study and if there is follow-up.

You can tell your study doctor at any time that you do not want your samples to be used and ask that they be destroyed. If you ask for this, study tests will be done, but samples will not be used for future research. Any information collected from your samples before you asked that they be destroyed will be kept.

If you decide to stop taking part in the study, but do not ask that your samples be destroyed, the researcher may still use your samples for research until the end of the storage period.

New Findings
Any new important information that is discovered during the research study and which may influence your willingness to continue participation in the study will be provided to you.

Further Information about this study
Participation in this study is voluntary. Refusal to participate will result in no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty or loss of benefits.

A description of this clinical trial may be available on http://www.Clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Questions or Concerns
You can talk to your study doctor about any questions or concerns you have about this study or if you feel you have had a research-related injury. Contact your study doctor at the numbers provided on the first page of this consent form.

If you have questions about your rights while taking part in this study or afterwards, or any concerns or complaints about how the research is being conducted, please call the Institutional Review Board of The Guthrie Clinic at 570-887-4885 or leave a message at **www.guthrie.org/irb** . This website also contains links to federal regulations on the protection of human research participants.

Authorization (Permission) to use your health information for research purposes

By signing this form, you are agreeing to permit the study doctor and his/her colleagues to review information in your medical records to conduct this research study as described above. The information from your medical records to be used is: list PHI to be used

By signing this form, you allow the use of your health information to carry out the study by:

- the Study Doctor and the study staff, and
- other healthcare providers, such as labs, involved in the study.
- research monitors and auditors,
- The Guthrie Clinic Institutional Review Board,
- The Guthrie Clinic Administration and
- government agencies like the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)

Withdrawing permission

This permission allowing use of your tissue and information in your medical records for this research does not expire. However, if you decide now that your information can be used for research, you can change your mind at any time. You have the right to withdraw the permission at any time, and no additional efforts to collect individually identifiable health information about you will be made.. However, any information or research data obtained up to that time will be retained and used. If you decide to withdraw this permission, please notify the investigator in writing or write to Guthrie Clinical Research, Donald Guthrie Foundation, One Guthrie Square, Sayre, PA 18840

Your private information will not be disclosed outside of the organization (OR Your private information will be disclosed to _____(the recipients). There is a potential for the protected health information to be re-disclosed by the recipient and no longer protected by the HIPAA Privacy Rule.)

You have the right to refuse to sign this permission to use your health information. If you do not sign the permission, you may not participate in the research. Not signing this consent form and permission will not affect the present or future care you receive and will not cause any penalty or loss of benefits to which you are otherwise entitled.

You will receive a copy of this form.

Research Participant
By signing below, I certify that I have read or had read to me and understand this consent form. I have had an opportunity to ask the doctor all my questions concerning the research study, the risks, and benefits. I consent to the use of my tissue and information in my health record for the research described in this form and I authorize the use and disclosure of Protected Health Information as described in this form.

_____ _____ Date: __/__/___ Time: _____
Printed Name of Participant Signature of Participant or
Legally Authorized Representative

_____ _____
Printed Name of Legally Authorized Representative Relation to Participant

Witness (Guthrie Employee)
By signing below, I certify that:
The participant/authorized representative has read this form or had it read to him/her.
The participant/authorized representative expresses understanding of this form.
The participant/authorized representative has no further questions.

_____ _____Date:__/___/___ Time: _____
Printed Name of Witness Signature of Witness

Person Obtaining Consent
I hereby certify that the risks, benefits, alternatives, and risks of those alternatives of this study in this consent form have been discussed with the individual granting consent. It is my opinion that the person signing this consent form understands and comprehends all of the matters discussed.

_____ _____ Date: __/__/___ Time: _____
Printed Name of Person Obtaining Consent Signature of Person Obtaining Consent

****

Impartial Witness (when applicable)
If the consent form is read to the participant or legally authorized representative because the participant or legally authorized representative 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 read to, accurately explained to, and apparently understood by the participant. The participant freely consented to be in the research study. I confirm that I was present during the entire informed consent discussion.

_____ _____ Date: __/__/___ Time: _____
Printed Name of Impartial Witness Signature of Impartial Witness

Signature page to be used if all eligible participants must be able to read and consent on their own behalf

Research Participant
By signing below, I certify that I have read and understand this consent form. I have had an opportunity to ask the doctor all my questions concerning the research study, the risks, benefits, alternatives, and risks of those alternatives. I consent to participate in the research described in this form, and I authorize the use and disclosure of Protected Health Information as described in this form.

_____ _____Date: __/__/___ Time: _____
Printed Name of Participant Signature of Participant

Witness (Guthrie Employee)
By signing below, I certify that:
The participant has read this form.
The participant understanding of this form.
The participant has no further questions.

_____ _____ Date: __/___/___ Time: _____
Printed Name of Witness Signature of Witness

Person Obtaining Consent
I hereby certify that the risks, benefits, alternatives, and risks of those alternatives of this study in this consent form have been discussed with the individual granting consent. It is my opinion that the person signing this consent form understands and comprehends all of the matters discussed.

_____ _____Date: __/__/___ Time: _____
Printed Name of Person Obtaining Consent Signature of Person Obtaining Consent