The Guthrie Clinic
One Guthrie Square
Sayre, PA 18840

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 subject}. 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 {…}. Tissue samples will not have your name or any identifying information. Any tissue remaining after the studies are completed will be discarded. Your tissue will not be sold.

About {anticipated number} people will take part in 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.

Using Information in Your Medical Record

We would like to use information in your medical record to make our laboratory findings more useful. Information about you will be treated in strict confidence to the extent required by law. Information in your medical records that could identify you will not be shared with anyone outside of The Guthrie Clinic.

Representatives from the Institutional Review Board of The Guthrie Clinic (a group of people who review the research to protect the rights of participants), The Guthrie Clinic Administration and federal regulatory agencies may inspect research records that could reveal your identity. These persons are bound by confidentiality regulations.

Your authorization to use information in your medical records will not have an expiration date. However, if you decide now that your tissue and medical record can be used for research, you can change your mind at any time. However, any information or research data obtained up to that time will be retained and used. If you decide to cancel the use of your tissue or medical record, write to Guthrie Clinical Research, Donald Guthrie Foundation, One Guthrie Square, Sayre, PA 18840.

Costs

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

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.

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.

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.

Questions or Concerns

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor by calling Guthrie Clinical Research at 570-887-6072 or 1-800-836-0388.

Other questions, concerns or complaints

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 Chairman of 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.

You will receive a copy of this form.

Research Subject

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 that my tissue specimens may be transferred to the Guthrie Foundation for research processing. I consent to the use of my tissue and information in my health record for the research described in this form.

_____ _____ Date: __/__/___ Time: _____

Printed Name of Subject | Signature of Subject or Legally Authorized Representative

_____ _____

Printed Name of Legally Authorized Representative | Relation to Subject

Witness (Guthrie Employee)

☐Yes ☐ No The patient/authorized representative has read this form or had it read to him/her.
☐Yes ☐ No The patient/authorized representative expresses understanding of this form.
☐Yes ☐ No The patient/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

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Impartial Witness **(when applicable)**

If the consent form is read to the subject or legally authorized representative because the subject 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 subject. The subject 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