CONSENT FORM FOR SPECIMEN STORAGE

Study Title:

Principal Investigator:

Type of Specimen to be Stored:

Method of Obtaining Specimen:

Place Where Specimen Will Be Stored:

Participant's Name:

INTRODUCTION

You are being (or have been) asked to participate in a research study. Another part of this study is asking your permission to store your specimen for future research. "Specimen" means body or organ tissue, blood, or other bodily substances researchers feel are important to study in order to better understand disease processes. You may choose to participate in this specimen storage part of the study or you may refuse. Your decision is entirely up to you. You will receive treatment and may participate in the research study whether or not you participate in the specimen storage.

A description of this clinical trial will 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.

You can also visit the National Cancer Institute's Web site at *http://www.rtog.org/tissue%20for%20research_patient.pdf* to read or print a new brochure called "How is Tissue Used for Research".

A procedure required (or will require) a specimen be removed from your body to study, treat, or prevent your disease. Your doctor is asking you to give your permission to store your specimen for future research.

PURPOSE

Future research on your specimen may aid in the development of new diagnoses, treatment and cures, as well as better scientific understanding of various diseases. If you give your permission to store your specimen, you may choose to allow your specimen to be studied only for research on your disease or you may choose to allow your specimen to be studied for various diseases.

PROCEDURES

Whether or not you agree to the use of your specimen will not affect the diagnosis or current treatment of your medical condition. If you give your permission to store your specimen, it will be sent to the place mentioned above and stored there for future research. Once your specimen is sent away, you give up any control of your specimen.

RISKS

The use of your specimen will not affect the diagnosis, treatment or follow-up of your medical condition. Information gained from this future research will not be shared with you or your doctor. The greatest risk is the release of information from your health records. The records about your specimen are considered confidential (private), but this confidentiality cannot be guaranteed.

PLEASE NOTE: The following language must be inserted for studies with genetic research:

A new 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 making a decision 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 by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does ***not*** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

BENEFITS

There are no direct benefits to you for participating in the specimen storage part of this study. The information gained from your specimen may possibly benefit others for the early detection, diagnosis, treatment or cure of various diseases.

COSTS AND COMPENSATION

There is no cost to you for participating in the specimen storage part of this study. You will not be compensated (paid) for participating in the specimen storage part of this study. The specimen donated by you may be used to develop new technologies, treatments or medications for different diseases. There may be financial gain by individuals or places using the knowledge or scientific information gathered from research on your specimen. It is unknown whether you will be able to receive or participate in any financial compensation (payment) from any benefits received from this research.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. To evaluate the results of the study and for compliance with federal and

state law, your health information may be examined and copied by the Food and Drug Administration (FDA), other governmental regulatory agencies, the Institutional Review Board of the Greenville Hospital System, the study sponsor and the sponsor's authorized representative(s). This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

If you have any questions about the privacy of your health information please ask your study doctor.

VOLUNTARY PARTICIPATION

Your participation in the specimen storage part of this study is voluntary. You may choose to participate in the initial study, but not participate in the specimen storage. If you choose to participate in the specimen storage, you may ask to withdraw from this part of the study at any time, but there is no guarantee that your specimen can be returned. Your withdrawal from the specimen storage will involve no penalty or loss of benefits. Your refusal or withdrawal will not affect your relationship with your doctor or the Greenville Hospital System.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, ***<<<PI Name and Telephone Number>>>.*** You may also contact a representative of the Institutional Review Board of the Greenville Hospital System for information regarding rights to participants involved in a research study, or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

A survey about your experience with this informed consent process is located at the following website:

www.ghs.org/research

Participation in the survey is completely anonymous and voluntary and will not affect your relationship with your doctor or the Greenville Hospital System. If you would like to have a paper copy of this survey, please tell your study doctor.

CONSENT TO PARTICIPATE

My study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form, or it has been read to me, and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given a copy of my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I understand I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

I want to participate in the specimen storage part of this study.

☐ Yes ☐ No

If ***yes***, please answer the following:

1. My specimen may be kept and used only for research for my disease.

   ☐ Yes ☐ No

   OR

2. My specimen may be kept and used for research for my disease and other various diseases.

   ☐ Yes ☐ No

3. I may be contacted in the future.

   ☐ Yes ☐ No

_____
Printed Name of Participant/Parent/Guardian

_____ _____ _____
Signature of Participant/Parent/Guardian Date Time

_____ _____ _____
Signature of Witness Date Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of this study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_____ _____ _____

Signature of Investigator Date Time

Principal Investigator: *List PI name and telephone number*

Co-Investigators: *List all Co-Investigator names and telephone numbers*