LOMA LINDA UNIVERSITY

Cancer Center

TITLE: Loma Linda University Cancer Center biospecimen laboratory – specimen collection protocol

PRINCIPAL INVESTIGATOR: Mark E. Reeves, M.D., PhD

SUBJECT INFORMATION AND CONSENT FORM FOR BIOSPECIMEN LABORATORY

In this document, "you" and "your" refer to the person who may participate in biospecimen banking for the Biospecimen Laboratory. "Research" refers to tests and/or studies conducted for non-commercial and/or commercial purposes.

Key Information for You to Consider

- **Voluntary Consent**. You are being invited to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research study is to help find out more about what causes cancer, how to prevent it and how to treat it.
- **Duration.** If you agree to participate in this program, you will stay in the system indefinitely, unless you want to be withdrawn from the study. Your specimen will stay in the system until it has been consumed.
- **Procedures and Activities.** You will be asked to donate specimens such as a small amount of blood, bone marrow, urine, or saliva. If you agree to participate in this program, the part of the specimen that would usually be thrown away will instead be stored in the Biospecimen Laboratory and used for research.
- **Risks.** The greatest risk to you is the release of information from your health records. LLUCC will protect your health information so that your name, address and phone number will kept private.
- **Benefits**. Although you will not benefit from this study, the scientific information we learn from the study may help find out more about what causes cancer, how to prevent it and how to treat it.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

INTRODUCTION

This is a research study involving human subjects. Your study doctor will explain the research study to you. Research studies include only subjects who choose to participate. Your study doctor and study staff will discuss the details outlined in this consent and answer your questions to your satisfaction. Please take your time to make your decision about participating. You may discuss your decision with your friends and family.

A Seventh-day Adventist Institution
CANCER CENTER CLINICAL TRIALS UNIT | 11175 Campus Street, CSP-11005, Loma Linda, CA 92350
(909) 558-4050 · *fax* (909) 558-0702 · www.llucc.org

WHY IS THIS STUDY BEING DONE?

Research on human specimens, such as tissues, blood, bone marrow, urine, saliva, pap smear, fluid from the abdomen or lungs, and Cerebrospinal fluid can help to find out more about what causes cancer, how to prevent it and how to treat it and other related diseases. Such specimens may be donated for research on cancer genetics and how diseases are passed on in families. Research done with these specimens is not likely to help you directly but may help people with cancer or other related diseases in the future.

You are invited to participate in Loma Linda University Cancer Center (LLUCC) Biospecimen Laboratory program, because you have been diagnosed with cancer, are being tested for a diagnosis, or have a related disease. As part of your routine medical care, you have had or will have a procedure to remove some or all of the tumor, or to take some of your blood, bone marrow, urine, saliva, pap smear or fluid from your abdomen and/or lungs. Each of these items is called a "specimen."

Sometimes specimens are stored in case they are needed later for the patient's care. The rest of the specimen that is not needed is usually thrown away. If you agree to participate in this program, the part of the specimen that would usually be thrown away will instead be stored in the Biospecimen Laboratory and used for research. Also, once specimens stored for your care is no longer needed, it will be given to the Biospecimen Laboratory and used for future research.

HOW WILL I BE INVOLVED?

You may be asked to donate a small amount of blood, bone marrow, urine, or saliva. Such blood samples (about 4 tablespoons) will be drawn by trained personnel at Loma Linda University Medical Center (LLUMC) at the same time you are having a routine blood draw to minimize possible discomfort or pain.

Biospecimen Laboratory personnel may re-contact you and ask you for a second donation of blood (1 tablespoon), urine, or saliva during or after your treatments. Again, such blood collections will take place at the same time it is drawn for your regular medical care. Blood donations will not be requested if your doctor thinks it will cause you any additional risk, discomfort, or pain.

Health information resulting from your care here at Loma Linda University Health (LLUH) entities may be collected from your medical records and this data will be saved in the Biospecimen Laboratory's password protected database.

In the event the laboratory moves, the LLUCC scientific committee will identify appropriate laboratory space for ongoing data management or handling of all banked specimens. In the event the laboratory closes, authorized personnel will be responsible for destroying all specimen samples and data.

The results of the research done using your specimens and data could be used for future research purposes. The results will not be given to you or your regular doctor and will not be put in your health records.

Many different kinds of studies use human specimens. Researchers at Loma Linda University Health entities or researchers at outside entities may request your specimens and data for research. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure different cancers. In the future, some of the research may help to develop new products, such as tests and drugs. You will not be paid for donating your specimens and data. If any new products, tests or discoveries, resulting from research using your specimen turn out to be valuable, that discovery will belong to Loma Linda University Health, or an outside entity, you will not share in any money.

WHAT COSTS ARE INVLOVED?
There are no costs to you for donating your specimens.

WILL STUDY STAFF RECEIVE PAYMENT?
LLUCC may receive payment from other outside entities requesting your specimens and data in order to cover the costs of collecting and storing the specimens.

RISKS
This study poses no greater risk to you than what you routinely encounter in day-to-day life. Participating in this biospecimen program exposes you to minimal risk of breach of privacy. The greatest risk to you is the release of information from your health records. To minimize this risk, LLUCC will protect your health information so that your name, address, and phone number will be kept private. No information identifying you will be released to researchers. Your privacy rights will be protected as described in the attached Authorization for Use of Protected Health Information. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will not be identified by name in any publications describing the results of this study. A secure database of your medical data associated with each tissue stored in the Biospecimen Laboratory will be maintained to protect your confidentiality and to facilitate optimal matching of specimen to specific research requirements. A limited number of individuals in Biospecimen Laboratory will have access to this database.

WILL THERE BE ANY BENEFIT TO ME OR OTHERS?
Although you will not benefit from this study, the scientific information we learn from the study may help find out more about what causes cancer, how to prevent it and how to treat it.

PARTICIPANTS RIGHTS
Participation in this program is voluntary. Your decision whether or not to participate or withdraw at any time will not affect your ongoing medical care/relationship to your doctor(s) and will not involve any penalty or loss of benefits to which you would normally receive.

If you change your mind about having your specimen(s) and data used in any future research, contact the Biospecimen Laboratory staff at 909-651-5082, and any specimen(s) and data that have not already been used in research can be disposed of. Any specimen(s) and data that have already been sent to a researcher within Loma Linda University Health, entities or outside entities cannot be returned and may continue to be used.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?
You will not be paid to participate in this research study.

HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not prohibit discrimination on the basis of an already manifest genetic disease or disorder. This means if you have a diagnosis and/or are being treated for a genetic condition, a health insurer may use the information to determine eligibility or rates. Also, GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to:
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf or CalGINA:
http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf

Certificate of Confidentiality from the National Institutes of Health:

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information of suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

IMPARTIAL THIRD PARTY CONTACT

If you wish to contact an impartial third party not associated with the Biospecimen Laboratory regarding any questions about your rights as a research subject or to report any complaint you may have about this program, you may contact the Office of Patient Relations, Loma Linda University Medical Center, 11234 Anderson Street, Loma Linda, CA 92354; (909) 558-4647 or email: patientrelations@llu.edu for information and assistance.

LOMA LINDA UNIVERSITY
Cancer Center

INFORMED CONSENT

By signing this consent form, I acknowledge that I have read this consent form or it was read to me and it includes an explanation of the nature of biospecimen banking, side effects and benefits that may occur from participation. Mark E. Reeves, M.D., Ph.D. is the leading investigator at Loma Linda University Cancer Center. I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me. I have been given the opportunity to ask questions concerning this program and they have been answered to my satisfaction. If I have additional questions, I may speak with the doctor and/or staff who explained the Biospecimen Laboratory to me by contacting the Loma Linda University Cancer Center during routine office hours by calling (909) 651-5082. I agree to participate in any additional studies where I selected "yes". I hereby give voluntary consent to participate in the Biospecimen Laboratory. Signing this document does not waive my rights nor does it release the investigators or institution from their responsibilities. I agree that my protected health information may be used for the research purposes as described in this consent and in the attached "Authorization for Use of Protected Health Information" form. As part of my participation in this program, I authorize the release of my specimens and data to the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University Health, Loma Linda University Cancer Center, Loma Linda University Health entities and any other outside entities and their authorized agents in accordance with this program requirements. I understand I will be given a copy of all 6 pages of this consent document.

☐ **YES** ☐ **NO** Additional specimen(s) (tissue/blood/bone marrow/urine/saliva/CSF/pap smear/fluid from abdomen or lungs) may be taken for future research.

☐ **YES** ☐ **NO** Someone from LLUCC may contact me in the future to follow up and gather more information from me or ask me to participate in more research studies.

☐ **YES** ☐ **NO** Any processed specimens kept by the hospital pathology that may no longer be needed for my care may be used for future research.

☐ **YES** ☐ **NO** Any specimens can be used for future genetic research.

☐ **(Check if applicable)** This study has been explained to my child at a level that he/she can comprehend and I give permission for my child to participate in the Biospecimen Laboratory.

Subject(Print Name)	Subject Signature (if 12 years old or older)	Date / Time AM / PM
Parent /Guardian (Print Name) (if subject is under 18 years old)	Parent/Guardian Signature (if subject is under 18 years old)	Date / Time AM / PM
Signature of Legally Authorized Representative	Printed Name of Legally Authorized Representative	Date / Time AM / PM

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied and that the subject has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions were answered.

Doctor or Designee (Print Name)	Doctor or Designee Signature	Phone
Date	Time AM / PM	

IRB #58238

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI) for Research Purposes

Human Research & Compliance
LOMA LINDA UNIVERSITY HEALTH | Office of the Vice President of Research Affairs
11219 Anderson Street, Loma Linda CA 92354
(909) 558-4531 (voice) e-mail: irb@llu.edu

TITLE OF STUDY:	Loma Linda University Cancer Center biospecimen laboratory – specimens collection protocol
PRINCIPAL INVESTIGATOR:	Mark E. Reeves, M.D., Ph.D.
Others who will use, collect, or share PHI:	Authorized research personnel at Loma Linda University Cancer Center (LLUCC)

The study named above may be performed only by collecting and using your personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: your name, address, telephone number, biospecimens, date of birth, research and medical records and charts, including the results of all tests and procedures performed.

The individual(s) listed below will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University Health, Loma Linda University Cancer Center, Loma Linda University Health entities and any other outside research entities and their authorized agents.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk. The study doctor and study personnel may use the results of these tests and procedures to treat you and to complete this research project.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international "protected health information" (PHI) regulations such as the federal privacy rule.

You may not be permitted to access (review or copy) your health information created during this research study while the research study is in progress. You may be entitled to access your health information once the research study is completed.

This authorization does not expire and will continue indefinitely unless you notify the study researchers that you wish to withdraw it.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time. To withdraw your permission, please contact the study doctor or study personnel at 909-558-4050.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to participate in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Subject *or* Subject's Legal Representative	Date / Time AM/PM
Printed Name of Subject *or* Legal Representative (if any)	Representative's Authority to Act for Subject