

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER IN NEW ORLEANS



Health Sciences Center  
TULANE CANCER CENTER

TULANE UNIVERSITY HEALTH SCIENCES CENTER  
Consent to Participate in Research

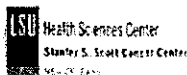
1. **Study Title:** Louisiana Cancer Research Consortium: Biospecimen Core Laboratory

2. **Performances Sites:** Earl K. Long Medical Center  
Ochsner Medical Center-Kenner  
Ochsner Medical Center  
University Hospital  
Tulane University Health Sciences Center  
Tulane-Lakeside Hospital

3. **Names and telephone numbers of Investigators:**

**Principal Investigator(s):** Arnold H. Zea, Ph.D.  
Louisiana State University Health Sciences Center  
Stanley S. Scott Cancer Center  
533 Bolivar St. Room: 453  
New Orleans, LA 70112  
(504) 599-0906

Krzysztof Moroz, MD  
Tulane University School of Medicine  
Department of Pathology SL79  
1430 Tulane Avenue  
New Orleans, LA 70112  
(504) 988-6199



IRB Approval

6/10/10  
6/9/11

Syn By



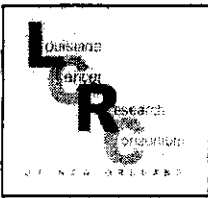


**Co-Investigators at the TUHSC and the LSUHSC:**

Donald Beahm, M.D. Department of Otorhinolaryngology	504-568-4785
Clay Boyd, M.D. Department of Urology	504-568-2207
Joseph F. Buell Section of Surgery- Abdominal Transplant	504-988-7867
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Melanie A. Edwards, M.D. Section of Thoracic Surgery	504-568-4750
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Steven D. Jones, M.D. Section of General Surgery	504-988-8100
Emad Kandil, M.D. Section of Endocrine Surgery	504-988-7407
Stephen Lacour, M.D. Department of Urology	504-568-2207
Benjamin R. Lee, M.D. Department of Urology	504-988-2750
Alan Marr, M.D. Department of Surgery	504-568-4743



Andrew McWhorter, M.D. Department of Otolaryngology, Head, and Neck Surgery	504-568-4785
Krishnarao Moparty, M.D. Department of Urology	504-988-2794
Daniel W. Nuss, M.D. Department of Otolaryngology, Head, and Neck Surgery	504-568-4785
Anna Pou, M.D. Department of Otolaryngology, Head, and Neck Surgery	504-569-4785
Oliver Sartor, M.D. Section of Hematology & Medical Oncology	504-988-5482
Douglas P. Slakey, M.D., FACS, M.H.A. Chairman, Department of Surgery	504-988-5336
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Raju Thomas, M.D., FACS, M.H.A. Chairman, Department of Surgery	504-988-2750
Rohan R. Walvekar, M.D. Department of Otolaryngology, Head, and Neck Surgery	504-568-4785
Marcus L. Ware, M.D., Ph.D. Department of Neurosurgery	504-988-5565
Michael Weaver, M.D. Section of Cardiothoracic Surgery	504-988-7520
Jane Wey, M.D. Section of Surgical Oncology	504-568-4750
Chris Winters, M.D. Section of Urology	504-412-1600
Mary Joe Wright, M.D. Section of Breast Surgery	504-988-8100



Vladimir Zuzukin, M.D. 504-568-4785  
Department of Otolaryngology, Head, and Neck Surgery

#### **4. Purpose of the Study:**

The purpose of this research study is to create an ongoing multi-institutional biospecimen repository (tumor bank) for studying various cancers found in the people of Southeastern Louisiana. Once tissue is removed from a person for diagnosis or treatment, it is usually thrown away. By donating this tissue to the Biospecimen Core Laboratory (BCL) of the Louisiana Cancer Research Consortium (LCRC), research into a cancer's cause, development and possible treatment can happen. You will be asked to donate tissue, normal and suspected cancerous, and/or blood and urine in addition to completing a questionnaire, only if you choose to volunteer for the study.

For the patients for whom blood only is being removed, the blood will be obtained from a standard blood draw. If this is for a biopsy or surgical procedure, no extra tissue will be removed other than what is required for your diagnosis or treatment. If you choose to donate, the BCL of the LCRC will store your samples. Your specimen will be used only for research and will not be sold. The research done with your specimen may help to develop new cancer treatments in the future. In the future, some of the 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 may look for genetic causes and signs of diseases if you agree to permit this.

#### **5. Description of the Study:**

You are being asked to take part in a research study that collects information about you, part of your tumor tissue, part of your normal tissue and/or blood and urine. If you agree to take part, you will also be asked to donate small pieces of your tumor tissue, normal tissue, blood and urine to the LCRC.

For biopsies or surgeries, the samples will be obtained from the biopsy of your tumor that has already been performed or from a surgery your doctors choose to perform on you. No more tissue will be requested other than those that would have been collected for either diagnostic or treatment purposes. Each piece of tissue will be frozen and delivered to the Biospecimen Core Laboratory (BCL).

If a blood sample is obtained, a trained phlebotomist (professional blood drawer) will draw 50 milliliters (about 5 tablespoons) of blood from your vein and collect it into a sterile tube. The blood will be collected either while you are under anesthesia during the procedure or prior to the surgery during a regular visit to the clinic. A small container will be provided to you to collect urine.

Your tissue and/or blood and urine samples will be kept at the BCL for research. Future plans for the collected samples include growing cell lines from some of the cells of the



collected tissues, genetic studies using DNA extracted from both tumor tissue and/or blood and/or molecular studies of proteins and/or other biochemical studies. Even if your samples are used for this kind of research, the results will not be put in your health record.

Researchers contact the Biospecimen Core Laboratory and request samples for their studies. The Tissue Committee of Biospecimen Core Laboratory reviews the way that these studies will be done, and decides if any of the samples can be used. The Biospecimen Core Laboratory collects the specimen and information about you and sends them to the researcher. The Biospecimen Core Laboratory will not send your name, address, phone number, social security number or any other identifying information to the researcher.

#### **6. Benefits to the Subject:**

There are no direct benefits for study participants. Information gained from the research could help understand disease causes, prevention, treatment and possible cures for other people. Some of these include finding the causes of diabetes, cancer, and heart disease, or finding genetic links to Alzheimer's.

You will not receive the results of research done with your specimen. This is because research can take a long time and 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 will not affect your care right now, but they may be helpful to people like you in the future.

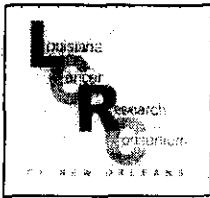
#### **7. Risks to the Subject:**

The risks for tissue collection include the same risks associated with the procedure you are already undergoing for treatment. A minor risk is associated with drawing blood. Minor pain, swelling, and/or minimal bruising can develop in reaction to a blood draw. Some patients may feel lightheaded and may even faint. A slight risk of infection also exists.

One risk is the release of information from your health records. Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but 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. We will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

#### **8. Alternatives to Participation in the Study:**

Participation in the study is completely voluntary. It includes adults and minor subjects with permission of their parents or legal guardians.



### **9. Subject Removal:**

You may be removed from the study if there is too little tumor to perform the study. If the pathologist feels that there is insufficient "extra" tissue available for tissue banking this may make you ineligible for the tissue bank and if no other information or specimens are obtained you would be withdrawn.

### **10. Subjects Right to Refuse to Participate or Withdraw:**

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which the subject is, otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If you do decide to withdraw, you will be asked to sign a form that states your decision. Your decision about donating samples will not affect your participation in any other research studies.

If you decide now that your tissue can be kept for research, you can change your mind at any time. Just contact Dr. Arnold Zea at (504) 599-0906 or Dr. Krzysztof Moroz at (504) 988-6199 and let one of them know that you do not want us to use your tissue. Then the tissue will no longer be used for research. Your tissue will be discarded and destroyed via incineration.

### **11. Subjects Right to Privacy:**

The results of the study may be released to the funding agency, the LCRC. The results of the study may be published. The privacy of subjects will be protected and they will not be identified in any way. Information that could be used to identify you will be kept in secure storage by Biospecimen Core Laboratory and will not be released to others. Information from your medical record and the donated tissue and blood samples will be identified by a research code. The list which links the research code to your name will be maintained in a password protected database, accessible only to researchers associated with the LCRC.

A secure database will be maintained. Confidential information obtained from the questionnaires and various tests will be kept in a coded form and not attached to your name. A unique study ID number will link your confidential information to your samples. Only qualified researchers will have access to the database. Results from various tests will not be put in your medical record. No information that could identify you will ever be released to others. Samples will be used only for research and will not be sold.

### **12. Release of Information:**

The medical records related to the study as well as the follow-ups will be available in the future to investigators at LSU or Tulane and to the FDA. In addition it may be necessary for the LSU Health Sciences Center's Institutional Review Board and/or the Tulane University Institutional Review Board to inspect these records. Records will not be



released to others unless required by law. Insurance companies will not be allowed access to any individual results nor will they be allowed access to anonymised data. Current and future employers will not be able to gain access to the information.

### **13. Financial Information:**

Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar illnesses. The costs of all other medications, physician visits procedures, and study-related and unforeseen complications will be met by you. You will get no compensation for taking part in this study. Every effort to prevent injury that could result from this study will be undertaken by the investigators. Financial compensation is not available in the event of physical injury, side effects, or death resulting from this research study. If any complications or injuries occur, emergency care and hospitalization will be billed to you as part of the medical expenses. No money will be provided as compensation for a research related injury, nor is monetary compensation available for wages lost because of injury, nor is any other financial compensation available. It is possible that information obtained from this study or future study could be commercially used in the future. Tissue obtained from the subject in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to the subject should this occur. Pharmaceutical and other biotech companies will be able to use collected specimens only if the donor answers "Yes" to the question about "for profit" company on the Research Consent Form.

Louisiana State University Health Sciences Center, Tulane University Health Sciences Center, and the Louisiana Cancer Research Consortium will be the legal owner of the database and samples. Participants will not have property rights in the samples. Louisiana Cancer Research Consortium will serve as the "steward" of the resource, maintaining and building it for the public good in accordance with the mission of the Biospecimen Core Laboratory: *"To collect high quality samples of normal and diseased human material with appropriate clinical annotation and make these materials available to qualified researchers at Louisiana Cancer Research Consortium while ensuring the informed consent, safety, and anonymity of all donors"*.

### **14. Signatures:**

The study has been discussed with me and all my questions have been answered. Additional questions regarding the study should be directed to investigators listed on page 1 of this consent form. If I have questions about my rights or other concerns I can contact the IRB of the LSU Health Sciences Center at (504) 568-4801 or the IRB at Tulane University Health Sciences Center at (504) 988-2665. I agree with the terms above and acknowledge I have been given a copy of the consent form.

In order to update any pertinent clinical information that may be needed, you may be contacted by telephone approximately every six to twelve months. If you do not wish to be contacted, it will not affect your treatment or your participation in this study.



**Please circle the appropriate response:**

1. I give permission for one of the investigators to contact me in the future by telephone or letter.  

Yes      No
2. My medical records may be examined to link medical information with my sample.  

Yes      No
3. My samples may be used by a "for profit" company (such as a pharmaceutical company).  

Yes      No
4. My samples may be used in the future for other purposes related to cancer research  

Yes      No

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Consent Administered by

\_\_\_\_\_  
Date



The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to participate.

\_\_\_\_\_  
Signature of Reader

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

The study subject is a minor and I certify that I am his/her legal guardian.

\_\_\_\_\_  
Legal Guardian Name

\_\_\_\_\_  
Legal Guardian Signature

\_\_\_\_\_  
Date

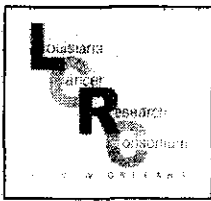
\_\_\_\_\_  
Minor's Name and Age

\_\_\_\_\_  
Minor's Signature

\_\_\_\_\_  
Date

Reason for not obtaining child's assent:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



**LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER NEW ORLEANS**

and

**TULANE UNIVERSITY HEALTH SCIENCES CENTER**

\*\*\*\*\*

**AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

(Instructions for Investigators: This form must be reviewed and signed by patients participating in research/clinical trials that require a signed Informed Consent document. These documents should be kept together. A copy of this Authorization and the Informed Consent document must be given to the subject and/or his/her representative.)

**Name of Research Project:** Louisiana Cancer Research Consortium: Biospecimen Core Laboratory

**Sponsor Name and Protocol Number if applicable:**

**Principal Investigator(s):** Arnold H. Zea, PhD.      **LSU IRB Number:** 6398

Krzysztof Moroz, M.D.      **Tulane IRB Number:** M0600

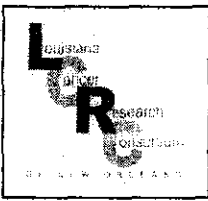
I hereby request and authorize the LSUHSC-NEW ORLEANS, and TUHSC to use and disclose protected health information from the record(s) of:

**Patient's Name:** \_\_\_\_\_

**Patient's Address:** \_\_\_\_\_

**Patient's Phone Number:** \_\_\_\_\_

Specifically, I request and authorize any part of my health information relevant to the research project, identified above and in the Informed Consent document, to be used and/or disclosed to the Principal Investigator identified above or his/her designee, in connection with the research project. I understand that this may include information relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse; and/or mental or behavioral health or psychiatric care.



I understand that copies of the records indicated above will be:

- Used by employees of LSUHSC-NEW ORLEANS and TUHSC including treatment providers, and/or other members of its workforce.
- Disclosed to government officials or government agencies, study sponsors, study monitors, or others responsible for oversight of the research project.
- Sent to collaborating researchers outside LSUHSC-NEW ORLEANS and TUHSC if and to the extent indicated in the attached Informed Consent document(s).
- Used and disclosed includes all information about you collected during your hospital treatments and any health information about you contained in medical records that may be used in the research study. For example, it would include your cancer diagnosis, staging information, prognostic information, type of treatments received.
- Used to create information that does not identify you. The de-identified data may be used and released by Researchers, including use for other research purposes.

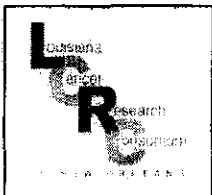
Signing this form, I will allow LSUHSC-NEW ORLEANS and TUHSC and its researchers to use or disclose my health information in connection with the attached Informed Consent and for the purpose of the research that is described in the Informed Consent.

In order to participate in this research study, you must sign this Authorization. However, you cannot be denied medical treatment because you did not sign this Authorization.

For example, the researchers may need the information to verify that I am eligible to participate in the study, or to monitor the results, including expected or unexpected side-effects or outcomes. Other University and government officials, safety monitors, and study sponsors may need the information to ensure that the study is conducted properly. Also, I understand that my health information may be disclosed to insurance companies or others responsible for my medical bills in order to secure payment.

I understand that any privacy rights not specifically mentioned in this Authorization are contained in the Notice of Privacy Practices that I received or will receive from the Principal Investigator or at the facility that I attend.

I understand that I may revoke this authorization at any time, except to the extent that LSUHSC-NEW ORLEANS and TUHSC has already relied on the authorization, by sending or transmitting a facsimile, a written notice to the contact person listed in the attached Informed Consent document(s).



I understand that if my information already has been included in a research database or registry as described in the attached Informed Consent document(s), LSUHSC-NEW ORLEANS and TUHSC considers itself to have relied on it, and therefore my information will not be removed from those repositories, unless I request that it be removed. Unless otherwise revoked, I understand that this authorization will not expire during the length of the research study. I understand that if I do not sign this form, I will not be able to participate in the above research study or receive the study-related interventions, but that LSUHSC-NEW ORLEANS and TUHSC cannot otherwise condition treatment on my signing this form. Also, even if you revoke this Authorization, the Researchers may still use and disclose the health information that they have already obtained as necessary to maintain the reliability of the research.

While the research study is in progress, my right to access any research records or results that are maintained by the facility may be suspended until the research study is over. If my access is denied, I understand that it will be reinstated at the end of the research study.

I understand the information disclosed by this authorization may be subject to re-disclosure by the recipient and no longer be protected by the Health Insurance Portability and Accountability Act. The LSUHSC and TUHSC facility, its employees, officers, and physicians are hereby released from any legal responsibility or liability for disclosure of the above information to the extent indicated and authorized herein.

I UNDERSTAND THAT THIS AUTHORIZATION SUPERSEDES ANY CONTRARY INFORMATION IN ANY OTHER DOCUMENTS I HAVE SIGNED RELATED TO THE ATTACHED STUDY.

Signature of Subject or Subject's Legal Representative: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name of Legal Representative (if any):

\_\_\_\_\_

Representative's Authority to Act for Subject (e.g., relationship to patient):

\_\_\_\_\_

Verification of Representative's Authority:

\_\_\_\_\_

- viewed driver's license
- viewed Power of Attorney
- viewed other (specify) \_\_\_\_\_



**Tulane University**  
Human Research Protection Program

*Tulane Human Research Protection Program  
Institutional Review Boards  
Biomedical  
Social Behavioral  
FWA00002055*

DATE: June 10, 2010

TO: Krzysztof Moroz, M.D.  
FROM: Tulane University Biomedical IRB

STUDY TITLE: [141014-2] Louisiana Cancer Research Consortium: Biospecimen Core Laboratory (M0600)

IRB REFERENCE #: M0600

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED

IRB APPROVAL DATE: June 10, 2010

IRB EXPIRATION DATE: June 9, 2011

Thank you for your recent Continuing Review/Progress Report submission. The Tulane University Institutional Review Board has granted approval for the above-referenced protocol together with:

- Informed Consent Form, LSUHSC-N.O. / TUHSC, LCRC Biospecimen Core Laboratory, LSU IRB#: 6398/Tulane IRB#: M0600, Consent Rev. Date: 04-14-10
- Protocol Rev. Date: 05-23-09
- LSU-HSC expedited IRB approval of research for approval period 10/12/2009 - 10/11/2010

in accordance with 45 CFR 46.111(a)(1-7) and 45 CFR 46.110. Children may be enrolled in accordance with 45 CFR 46.404, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 45 CFR 46.408. Please note the expiration date of the protocol above.

***As a reminder to Investigator: (1) As there is no formal DSMB assigned to this research project, it is the responsibility of the Investigator to provide data monitoring to ensure safety of subjects, and safety of the data collected in accordance with Federal regulation 45 CFR 46.111(a)(6); (2) Investigator to provide child assent for minors 7 - 17 years of age per Tulane University HRPP Policy, and Federal regulation.***

All research must be conducted according to the protocol that was approved by the IRB. Any proposed changes to the research must be submitted to the IRB for review and approved prior to implementation, unless a change is necessary to avoid immediate harm to subjects.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must

continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of their signed consent form.

Any Unanticipated Problems involving Risk to Subjects or Others, Deviations from the approved research, Non-Compliance, and Complaints must be reported to the IRB in accordance with Tulane HRPP policies and procedures. If this study includes ongoing oversight by a Data Safety Monitoring Board (DSMB) or other such committee, reports generated by the DSMB or oversight committee must be submitted to the IRB.

Continuations must be submitted in accordance with Tulane HRPP policies and procedures. The Continuing Review Form must be received by the IRB with enough time to allow for review and approval prior to the Expiration Date above. Please consult the IRB website and access the Submission Deadlines. Failure to submit the Continuing Review Form in a timely manner may result in the termination of IRB approval. When all study activities and data analysis have been completed, please notify the IRB within 30 days by submitting a Study Closure Form.

If you have any questions regarding this approval, please contact the IRB office at (504) 988-2665 or [irbmain@tulane.edu](mailto:irbmain@tulane.edu).

Sincerely,

/s/ Electronically signed  
Mark James, PhD

Please note that actual signature by the IRB Chair(s) is not required for this document to be effective since it is generated by IRBNet pursuant to the IRB Chair's electronic signature and approval. This process is consistent with Federal regulations and Tulane standard operating policies with respect to the IRB and Human Research Protection Office, which consider electronically-generated documents as official notice to sponsors and others of approval, disapproval or other IRB decisions. Please refer to the HRPO website at <http://tulane.edu/asvpr/irb> to refer to Tulane's Electronic Signatures and Records Policy.