SUCCESS OF ONE PAGE CONSENT AND BROCHURE FOR BIOSPECIMEN BANKING

B. Singh [1,2], N.Ziguridis[2], A. Ginsberg[2]

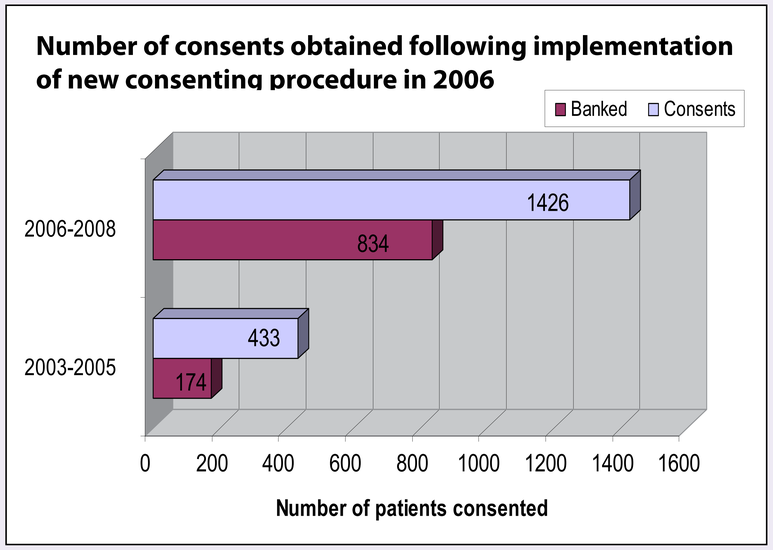
1Department of Pathology, 2 Tissue Acquisition and Banking Service, New York University Cancer Institute, New York University Langone Medical Center, New York.

Background:

HIPAA mandates that patients sign a separate Informed Consent Form (ICF) for donating biospecimens for research. This poses a significant challenge to the medical staff and may negatively impact accrual to biorepositories

Materials and Methods:

At NYU Cancer Institute, the traditional ten page ICF was reformatted as a tri-fold brochure and one page ICF in 2005. The brochure is given to patients during the office visit or at time of registration and the triplicate one-page ICF on the day of surgery. The brochure contains information regarding biospecimen banking and this process gives the patient ample time to read the material and contact biorepository personnel with any concerns. The triplicate, one page consent is signed by the patient on the day of surgery, one copy is inserted into the medical chart; the second copy is given to the patient and the third copy is attached to the surgical pathology requisition, which accompanies the specimen to the surgical pathology suite. This novel process has been used since 2006.



Brochure

This Authorization will not expire unless you revoke it in writing. You have the right to revoke your authorization at any time, except to the extent that NYU has already relied upon it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K. By signing this form you authorize the use and disclosure of the following information for this research:

- Your medical records
- Your research record
- Results of laboratory tests
- Clinical and research observations made during your participation in the research.

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research:

- Every research site for this study, including each site's research staff and medical staff
- Dr. Singh and his tissue acquisition team
- Every health care provider who provides services to you in connection with this study
- Any laboratories or other persons or organizations that analyze your study information for this research
- The National Institute of Health (NIH), its affiliates and the people and companies the sponsor uses to oversee, administer, or conduct the research
- The U.S. Food and Drug Administration (FDA) and other domestic and foreign regulatory agencies
- The members and staff of each Institutional Review Board (IRB) overseeing the study
- The study coordinator
- Members of the Tisch and Bellevue hospital staff responsible for administering clinical trials and handling pathology material
- Data safety monitoring boards, clinical events committees, and others authorized to monitor the conduct of the study

If any of the companies or institutions listed above merges or is sold during the course of this research, your Authorization will cover uses and disclosures of your protected health information to the new company or institution that assumes responsibility for the research.

I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:
All forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study. If you sustain any injury during the course of the research, please contact the Principal Investigator, Dr. Baljit Singh at the following telephone number: 212-263-0136 . If such a complication arises, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. You do not give up any rights to seek payment for personal injury by signing this form.

J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:
Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled. Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:
If you decide to take part in the study, you may withdraw from participation at any time without penalty. You may also withdraw your Authorization for us to use or disclose your protected health information for the study. If you do decide to withdraw your consent, as well as your Authorization, we ask that you contact Dr. Baljit Singh in writing and let him know that you are withdrawing from the study. His mailing address is Tisch Hospital, Room TH-468, 560 First Avenue, New York, NY 10016. Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

L. PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH:
I authorize the principal investigator and his or her co-investigators to contact me about future research within the NYUSM facility provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, then someone from Dr. Singh's staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project. Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the NYUSM facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

M. SEPARATE CONSENT AUTHORIZATION IN THE FUTURE:
If at a future date, you are asked to consent to participate in a separate research study that requires use of this same banked tissue, we will make every attempt to enable transfer of the tissue to this separate research study. In that case, the tissue and data will be handled according to the guidelines in the more recent consent form that you sign for that study (which will supercede those detailed in this consent form).

N. CONTACT PERSON(S):
For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-263-4110.

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to study drug or procedure, or believe that their has been a breach of privacy or confidentiality in connection with this research, please contact the Principal Investigator, Dr. Baljit Singh at the following telephone number: 212-263-0136.

WHEN THE SUBJECT IS AN ADULT:
Notice Concerning HIV-Related Information: If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

* For subjects who may not be capable of providing informed consent, the signature of a legal representative is required. For a valid HIPAA authorization, the "personal representative" must have authority under state law to make health care decisions for the subject.

** When the elements of informed consent are presented orally to the subject or representative, a witness to the oral presentation is required.

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

Acquisition and Banking of Human Tissues and Serum Samples with applicable clinical data for the NYU Cancer Institute Tissue and Serum Bank

Principal Investigator:
Baljit Singh, MD

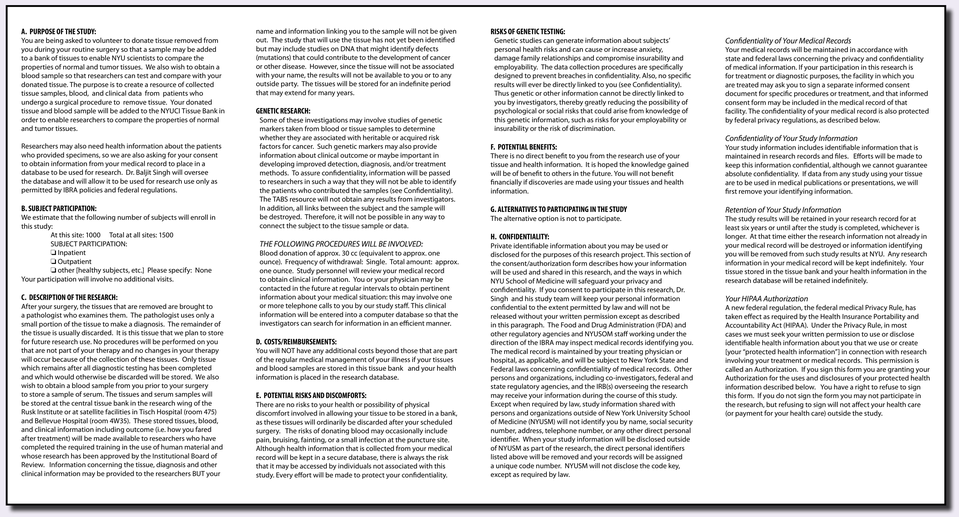
NYU School of Medicine

New York University
School of Medicine
550 First Ave.
Building #VET 10 West
NY, NY 10016

Phone: 212.263.4110
Fax: 212.263.4147

NYUSOM IRB APPROVED 2/28/08

NYU CANCER INSTITUTE



A. PURPOSE OF THE STUDY:
You are being asked to volunteer to donate tissue removed from you during your routine surgery so that a sample may be added to a bank of tissues to enable NYU scientists to compare the properties of normal and tumor tissues. We also wish to obtain a blood sample so that researchers can test and compare with your donated tissue. The purpose is to create a resource of collected tissue samples, blood, and clinical data from patients who undergo a surgical procedure to remove tissue. Your donated tissue and blood sample will be added to the NYUCI Tissue Bank in order to enable researchers to compare the properties of normal and tumor tissues.

Researchers may also need health information about the patients who provided specimens, so we are also asking for your consent to obtain information from your medical record to place in a database to be used for research. Dr. Baljit Singh will oversee the database and will allow it to be used for research use only as permitted by IBRA policies and federal regulations.

B. SUBJECT PARTICIPATION:
We estimate that the following number of subjects will enroll in this study:
At this site: 1000 Total at all sites: 1500
SUBJECT PARTICIPATION:
❑ Inpatient
❑ Outpatient
❑ other (healthy subjects, etc.) Please specify: None
Your participation will involve no additional visits.

C. DESCRIPTION OF THE RESEARCH:
After your surgery, the tissues that are removed are brought to a pathologist who examines them. The pathologist uses only a small portion of the tissue to make a diagnosis. The remainder of the tissue is usually discarded. It is this tissue that we plan to store for future research use. No procedures will be performed on you that are not part of your therapy and no changes in your therapy will occur because of the collection of these tissues. Only tissue which remains after all diagnostic testing has been completed and which would otherwise be discarded will be stored. We also wish to obtain a blood sample from you prior to your surgery to store a sample of serum. The tissues and serum samples will be stored at the central tissue bank in the research wing of the Rusk Institute or at satellite facilities in Tisch Hospital (room 475) and Bellevue Hospital (room 4W35). These stored tissues, blood, and clinical information including outcome (i.e. how you fared after treatment) will be made available to researchers who have completed the required training in the use of human material and whose research has been approved by the Institutional Board of Review. Information concerning the tissue, diagnosis and other clinical information may be provided to the researchers BUT your name and information linking you to the sample will not be given out. The study that will use the tissue has not yet been identified but may include studies on DNA that might identify defects (mutations) that could contribute to the development of cancer or other disease. However, since the tissue will not be associated with your name, the results will not be available to you or to any outside party. The tissues will be stored for an indefinite period that may extend for many years.

GENETIC RESEARCH:
Some of these investigations may involve studies of genetic markers taken from blood or tissue samples to determine whether they are associated with heritable or acquired risk factors for cancer. Such genetic markers may also provide information about clinical outcome or maybe important in developing improved detection, diagnosis, and/or treatment methods. To assure confidentiality, information will be passed to researchers in such a way that they will not be able to identify the patients who contributed the samples (see Confidentiality). The TABS resource will not obtain any results from investigators. In addition, all links between the subject and the sample will be destroyed. Therefore, it will not be possible in any way to connect the subject to the tissue sample or data.

THE FOLLOWING PROCEDURES WILL BE INVOLVED:
Blood donation of approx. 30 cc (equivalent to approx. one ounce). Frequency of withdrawal: Single. Total amount: approx. one ounce. Study personnel will review your medical record to obtain clinical information. You or your physician may be contacted in the future at regular intervals to obtain pertinent information about your medical situation: this may involve one or more telephone calls to you by our study staff. This clinical information will be entered into a computer database so that the investigators can search for information in an efficient manner.

D. COSTS/REIMBURSEMENTS:
You will NOT have any additional costs beyond those that are part of the regular medical management of your illness if your tissues and blood samples are stored in this tissue bank and your health information is placed in the research database.

E. POTENTIAL RISKS AND DISCOMFORTS:
There are no risks to your health or possibility of physical discomfort involved in allowing your tissue to be stored in a bank, as these tissues will ordinarily be discarded after your scheduled surgery. The risks of donating blood may occasionally include pain, bruising, fainting, or a small infection at the puncture site. Although health information that is collected from your medical record will be kept in a secure database, there is always the risk that it may be accessed by individuals not associated with this study. Every effort will be made to protect your confidentiality.

RISKS OF GENETIC TESTING:
Genetic studies can generate information about subjects' personal health risks and can cause or increase anxiety, damage family relationships and compromise insurability and employability. The data collection procedures are specifically designed to prevent breaches in confidentiality. Also, no specific results will ever be directly linked to you (see Confidentiality). Thus genetic or other information cannot be directly linked to you by investigators, thereby greatly reducing the possibility of psychological or social risks that could arise from knowledge of this genetic information, such as risks for your employability or insurability or the risk of discrimination.

F. POTENTIAL BENEFITS:
There is no direct benefit to you from the research use of your tissue and health information. It is hoped the knowledge gained will be of benefit to others in the future. You will not benefit financially if discoveries are made using your tissues and health information.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY
The alternative option is not to participate.

H. CONFIDENTIALITY:
Private identifiable information about you may be used or disclosed for the purposes of this research project. This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which NYU School of Medicine will safeguard your privacy and confidentiality. If you consent to participate in this research, Dr. Singh and his study team will keep your personal information confidential to the extent permitted by law and will not be released without your written permission except as described in this paragraph. The Food and Drug Administration (FDA) and other regulatory agencies and NYUSOM staff working under the direction of the IBRA may inspect medical records identifying you. The medical record is maintained by your treating physician or hospital, as applicable, and will be subject to New York State and Federal laws concerning confidentiality of medical records. Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of New York University School of Medicine (NYUSM) will not identify you by name, social security number, address, telephone number, or any other direct personal identifier. When your study information will be disclosed outside of NYUSM as part of the research, the direct personal identifiers listed above will be removed and your records will be assigned a unique code number. NYUSM will not disclose the code key, except as required by law.

Confidentiality of Your Medical Records
Your medical records will be maintained in accordance with state and federal laws concerning the privacy and confidentiality of medical information. If your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The confidentiality of your medical record is also protected by federal privacy regulations, as described below.

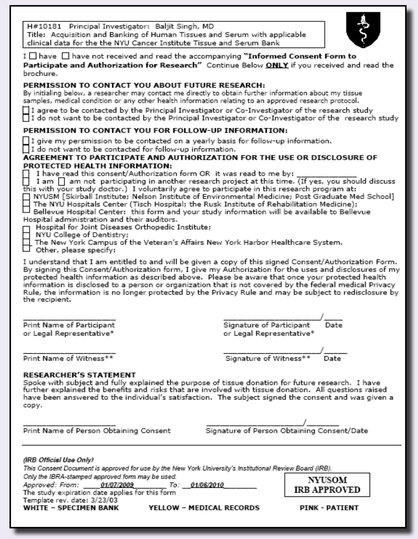
Confidentiality of Your Study Information
Your study information includes identifiable information that is maintained in research records and files. Efforts will be made to keep this information confidential, although we cannot guarantee absolute confidentiality. If data from any study using your tissue are to be used in medical publications or presentations, we will first remove your identifying information.

Retention of Your Study Information
The study results will be retained in your research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at NYU. Any research information in your medical record will be kept indefinitely. Your tissue stored in the tissue bank and your health information in the research database will be retained indefinitely.

Your HIPAA Authorization
A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, in most cases we must seek your written permission to use or disclose identifiable health information about you that we use or create [your "protected health information"] in connection with research involving your treatment or medical records. This permission is called an Authorization. If you sign this form you are granting your Authorization for the uses and disclosures of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not participate in the research, but refusing to sign will not affect your health care (or payment for your health care) outside the study.

One Page Informed Consent Form

(signed by patient on the day of surgery)



H#10181 Principal Investigator: Baljit Singh, MD
Title: Acquisition and Banking of Human Tissues and Serum with applicable clinical data for the the NYU Cancer Institute Tissue and Serum Bank

I ☐ have ☐ have not received and read the accompanying **"Informed Consent Form to Participate and Authorization for Research"** Continue Below **ONLY** if you received and read the brochure.

PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH:
By initialing below, a researcher may contact me directly to obtain further information about my tissue samples, medical condition or any other health information relating to an approved research protocol.
☐ I agree to be contacted by the Principal Investigator or Co-Investigator of the research study
☐ I do not want to be contacted by the Principal Investigator or Co-Investigator of the research study

PERMISSION TO CONTACT YOU FOR FOLLOW-UP INFORMATION:
☐ I give my permission to be contacted on a yearly basis for follow-up information.
☐ I do not want to be contacted for follow-up information.

AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:
☐ I have read this consent/Authorization form OR it was read to me by:
☐ I am ☐ am not participating in another research project at this time. [If yes, you should discuss this with your study doctor.] I voluntarily agree to participate in this research program at:
☐ NYUSM [Skirball Institute; Nelson Institute of Environmental Medicine; Post Graduate Med School]
☐ The NYU Hospitals Center (Tisch Hospital; the Rusk Institute of Rehabilitation Medicine);
☐ Bellevue Hospital Center; this form and your study information will be available to Bellevue Hospital administration and their auditors.
☐ Hospital for Joint Diseases Orthopedic Institute;
☐ NYU College of Dentistry;
☐ The New York Campus of the Veteran's Affairs New York Harbor Healthcare System.
☐ Other, please specify:

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form. By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures of my protected health information as described above. Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

Print Name of Participant or Legal Representative* _____ Signature of Participant or Legal Representative* _____ / Date

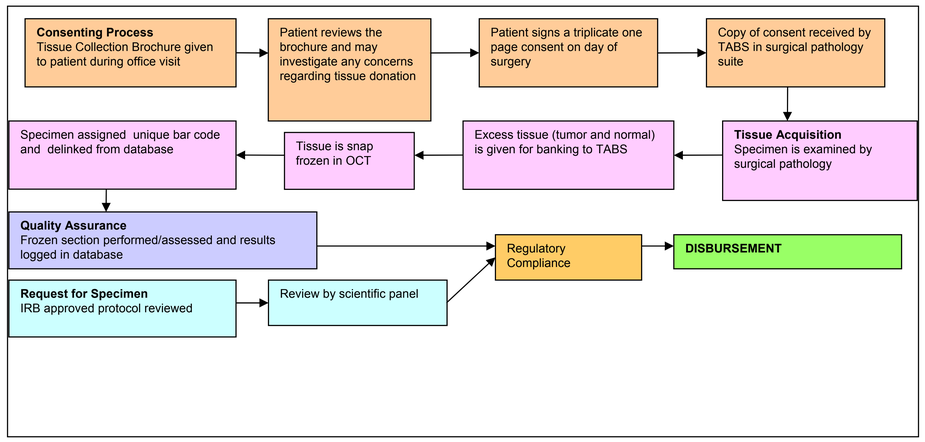
Print Name of Witness** _____ Signature of Witness** _____ / Date

RESEARCHER'S STATEMENT
Spoke with subject and fully explained the purpose of tissue donation for future research. I have further explained the benefits and risks that are involved with tissue donation. All questions raised have been answered to the individual's satisfaction. The subject signed the consent and was given a copy.

Print Name of Person Obtaining Consent _____ Signature of Person Obtaining Consent/Date _____ /

(IRB Official Use Only)
This Consent Document is approved for use by the New York University's Institutional Review Board (IRB):
Only the IBRA-stamped approved form may be used.
Approved: From: 01/07/2009 *To:* 01/06/2010
The study expiration date applies for this form
Template rev. date: 3/23/03
NYUSOM IRB APPROVED
WHITE – SPECIMEN BANK YELLOW – MEDICAL RECORDS PINK - PATIENT

NYUCI HIPAA Compliant Consenting Process



Results:

In a three year period (2003-2005), the ten page ICF was used to consent 433 patients with an average of 2.77 patients/week. After the implementation of the novel brochure and single page ICF format, 1426 patients were consented in the next three year period (2006-2008) with an average of 9.14 patients/week.

Conclusions:

A novel consenting mechanism with a brochure and one page consent has been successfully implemented at NYU Cancer Institute and has resulted in a significant increase in accrual to the Tissue Acquisition and Banking service core. The process is being replicated institute wide for accrual to all biorepositories at NYULMC.