

Columbia University Medical Center Consent Form

Attached to Protocol: IRB-AAAE3306

Principal Investigator: Wendy Chung (wkc15)

IRB Protocol Title: Biobank for facilitation of translational clinical research and individualized medicine

Consent Number: CF-AAAF3619

Participation Duration: One hour

Anticipated Number of Subjects: 10000

Contact

<u>Contact</u>	<u>Title</u>	<u>Contact Type</u>	<u>Numbers</u>
Wendy Chung	Assistant Professor	Principal Investigator	Telephone: 212-851-5313

Research Purpose

WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to establish a "biobank" for clinical research at Columbia University Medical Center. Biobanks are storage facilities that contain samples of blood, urine and tissues that are frozen for use in future research. Biobanks are especially useful to learn about diseases, possible treatments, including the role that genes play in human diseases.

The Columbia University Medical Center (CUMC) Biobank will collect materials that would otherwise be thrown away and share them with researchers who need them for their studies.

Information on Research

INTRODUCTION

The purpose of this form is to give you information to help you decide if you would be willing to have your child take part in a research project. This consent form includes information about:

- why the project is being done;
- the things that you and your child will be asked to do if your child is in the project;
- any known risks involved;
- any potential benefit; and
- options, other than taking part in this project, that you have.

The CUMC Biobank recruiter will discuss the project with you. If at any time you have questions about the project, please ask a member of the project team. Take all the time you need to decide whether you want your child to take part in this project.

Parental Consent



WHAT IS INVOLVED IN THIS PROJECT?

If you agree for your child to be involved in this project, left-over blood, urine, and/or tissues that were already being collected for medical tests (e.g., tests for anemia or blood sugar, urine tests for kidney function, biopsies of tissues) will be stored in the CUMC Biobank, where they will be frozen for use in future and/or genetic research. No extra blood, urine, or tissues will be taken from your child, beyond what is needed for your child's treatment, if your child joins the CUMC Biobank. The samples that are collected will be kept as long as possible.

Taking part in this project will require 30-60 minutes of your time or of your child's time, if your child is able to answer questions on his or her own. You or your child will be asked to complete a brief questionnaire about your child's age, sex, race/ethnicity, family medical history, smoking and alcohol consumption, health, environmental exposures, education, occupation (if any), and socioeconomic status. You or your child may also be contacted in the future to answer some of these same questions to see what has changed in your child's life over time. The information will be stored in a secure computer and identified only by a CUMC Biobank identification (ID) number. To help keep your child's samples and information secret, the link between your child's name and ID number will be kept in a separate computer, available only to CUMC Biobank personnel.

In addition, a computer will go through your child's medical record to collect information about your child (e.g., height, weight, blood pressure), family history of illness, conditions that your child has (e.g., high blood pressure), treatments that your child has received (e.g., medication or surgery), and results of laboratory and x-ray tests. The computer will separate that information from anything that would identify your child personally, such as your child's name, medical record number, address, etc. The medical information gathered by the computer will be stored in the same secure computer as the information from the questionnaire and also identified only by an ID number. It will be updated regularly.

When a researcher at Columbia University would like to use some of the samples for research, a CUMC Biobank committee will review the proposal to make sure that it is a good use of the samples. The researcher may be given part of your child's samples (the same sample can be used by many researchers), along with information in the computer about your child. However, no information about your child's identity or the identity of any other person whose samples may be studied will ever be released to the researchers.

Future testing and research may lead to the new tests and treatments having commercial value. Your child will not receive any payment that may result from this testing or research. You and your child will not be informed of your personal results of any studies using your child's samples, but will receive annual study newsletters of the results of studies resulting from the Biobank as a whole.

Risks

WHAT ARE THE RISKS OF THE PROJECT?

Loss of confidentiality

Parental Consent

A very small risk of taking part in this project is the possibility of a loss of confidentiality. Loss of confidentiality includes having your child's personal information shared with someone who is not part of the CUMC Biobank and was not supposed to see or know about your child's information. The study team plans to protect your child's confidentiality. Their plans for keeping your child's information private are described in the 'Confidentiality' section of this consent form.

Inconvenience

Although it is not a risk, taking part in this study involves the inconvenience of giving 30-60 minutes of your time to complete the questionnaire.

Benefits

ARE THERE BENEFITS TO TAKING PART IN THIS PROJECT?

Neither you nor your child will receive personal (direct) benefit from taking part in this project. However, the information collected from research made possible by the CUMC Biobank may help others in the future.

Alternative Procedures

This is not a treatment study. The alternative would be not to participate.

Confidentiality

WHAT ABOUT CONFIDENTIALITY?

We will do everything we can to keep your child's data secure, however, complete confidentiality cannot be promised. Your child's samples in the CUMC Biobank, your or your child's answers to the questionnaire, and the information obtained from your child's medical records will be assigned a Biobank (ID) code number, and separated from your child's name or any other information that could identify your child. The information will be stored in a secure computer. The link between any identifying information and your child's CUMC Biobank identification number will be kept in a separate computer, available only to CUMC Biobank personnel.

Despite all of our efforts, unanticipated problems, such as unauthorized access to a computer may occur. However, since identifying information and medical information will be kept on two separate secure computers, unauthorized access to both computers, which would allow your child's medical information to be linked to your child's identity, is highly unlikely.

The following persons and/or agencies will be able to look at and copy the records of your child's participation in this project:

- The investigator and other CUMC Biobank staff
- Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB')
- The United States Office of Human Research Protections ('OHRP')
- Other government regulatory agencies

Parental Consent

Compensation

WILL MY CHILD GET COMPENSATED?

Your child will be paid \$20 to compensate him or her for the time involved in completion of the questionnaire.

Additional Costs

WHAT ARE THE COSTS?

There are no costs to you for taking part in this project.

Voluntary Participation

DOES MY CHILD HAVE TO BE IN THE PROJECT?

Participation in the CUMC Biobank is voluntary. Refusal to participate will involve no penalty or loss of benefits to which your child is otherwise entitled. You (until your child turns 18) or your child may discontinue your child's participation at any time without penalty or loss of benefits to which your child is otherwise entitled. You (until your child turns 18) or your child may at any time request that your child's blood and/or any other sample collected (or the materials in it, including genetic materials) be removed from the CUMC Biobank and destroyed, and that your child's medical information be removed from the CUMC Biobank computers. Signing this form does not waive any of your legal rights. You will receive a copy of the consent for your records.

Additional Information

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions or your child is hurt while taking part in this research study, you should contact Wendy Chung, MD, PhD at 212-851-5313.

If you have any questions about your child's rights as a research subject, you should contact the Columbia University Institutional Review Board by phone at (212) 305-5883 or by email at askirb@columbia.edu.

More information about taking part in a research study can be found on the Columbia University IRB website at: <http://www.cumc.columbia.edu/dept/irb>.

STATEMENT OF CONSENT

I voluntarily consent to my child's participation in CUMC Biobank. I have read this consent form and understand the nature and the purpose of the CUMC Biobank. By signing and dating this consent form, I am agreeing to have my child's samples and nonidentifiable medical information stored and shared with researchers who are doing different kinds of medical research.

Signature

Parental Consent

Parent/Guardian
Print Name_____Signature_____Date_____

Person Obtaining Consent
Print Name_____Signature_____Date_____

Child
Print Name_____

Parental Consent