

Research Subject Informed Consent Form

Title of Study:	New York University Factors Influencing Reproductive Success and Time to Pregnancy (FIRST) Study
Principal Investigator:	Leonardo Trasande, MD Department of Pediatrics NYU School of Medicine 403 East 34 th Street, Room 115, New York, NY 10016 Work: (646) 501-2520 Fax: (646) 754-9688
Emergency Contact:	Linda Kahn, PhD, MPH (646) 630-5533

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary, which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research biobank is to collect, process, and store biological samples such as blood, urine, saliva, and other bodily material, along with environmental and medical information, from couples trying to become pregnant. Biological samples in this bank will be used mainly for research on fertility, pregnancy, and early risk factors for childhood and adult diseases. This research may lead to better and more effective treatment options and improvement in quality of life.

You have been asked to take part in this study because you and your partner are trying to become pregnant.

3. How long will I be in the study? How many other people will be in the study?

Your participation in this study will last until you become pregnant, or stop trying to become pregnant. Most couples become pregnant within 6-12 months, although some couples continue to try for longer.

We do not have a limit on the number of participants who can join the study.

4. What will I be asked to do in the study?

This research study will be conducted at NYU-affiliated hospitals and research centers.

For women, this study will involve an initial in-person baseline clinic visit when you enroll, one week of wearing three wristband monitors, dietary surveys, approximately weekly at-home urine collection, monthly telephone calls or emails, and additional clinic visits every 5 months if you are still trying to become pregnant. Participants will also be asked to complete a brief anonymous participant satisfaction survey. Those who conceive and deliver at a non-NYU hospital will also be contacted for an update on their pregnancy status approximately 20 weeks post-conception and after their estimated date of delivery.

When you enroll in this study, you will be asked to fill out a background questionnaire, provide biological samples, and have some measurements taken at home or at one of our clinic sites. We will collect blood, a urine sample, a saliva sample, hair and nail clippings, and ask you to swab your vagina and rectum. For the vaginal and rectal swabs, you will insert a Q-tip-like swab approximately 1.5 inches into your vagina or rectum, gently rotate, then remove. We will also take your weight, height, blood pressure, as well as perform a comprehensive sonographic assessment and measure your body composition and heart function. All specimens with the exception of blood can be collected at home, where you can also take your height, weight, and waist and hip measurements if you are unable to come in for a baseline visit. For the week following the visit you may be asked to wear three wristband monitors, which you will return to us in a postage-paid envelope. You will also be asked to complete a diet survey. After this first clinic visit, we will follow up with a phone call or email once a month asking if you are pregnant and for updates on some of your activities. Approximately once a week you will collect your first-morning urine and store it in a sealed container in your freezer. Once every 5 months, if you are not pregnant, you will return to the clinic to provide another set of biological samples and have measurements taken again. If you are unable to come to a baseline visit before conception, a baseline visit may be conducted post-conception. Toward the end of your participation, you will be asked to complete an anonymous patient satisfaction survey to help us improve the study for future participants.

The baseline questionnaire at your first visit will ask about your background, your partner, your reproductive and general health history, your sleep and activity level, what medications you may take, and environmental chemicals you may be exposed to in your everyday life. Each brief monthly follow-up questionnaire will ask if you are pregnant, your weight, and whether you have changed your behavior in certain areas (sleep, exercise, smoking, drinking, medication use). The questionnaire will also ask for the date of your last menstrual period and the dates on which you had unprotected intercourse, and/or fertility related procedures during that month (we will provide a calendar to help you keep track).

Your blood sample (4 tubes=less than 3 tablespoons) will be collected by a trained technician; you will provide urine the way you do at a normal doctor's visit; you will provide saliva by spitting into a small tube; and you will provide vaginal and rectal swabs in private using kits that we will give you. Height, weight, and blood pressure will be taken as at a normal doctor's visit. Body composition will be measured two ways: using a machine that calculates your percentage body fat, and using a tape measure and calipers, which measure the thickness of your skin at different parts of your body. Your heart function will be measured using two machines; each measurement takes approximately 60 seconds. The three wristbands will monitor: 1) your physical activity and sleep, 2) your exposure to air pollution, and 3) your exposure to chemicals in fabrics and building materials.

We are also asking for your permission to store some of your health information that may be relevant to your samples so that your samples will be more useful for research. We plan to continue to review your

medical record to update your health information in the biobank computer database. These reviews are conducted only to help us understand how the results of your sample tests relate to your other health information.

Our research biobank is located at New York University School of Medicine Langone Medical Center.

Information about Sample Storage

Your samples and information will be used mainly to advance the community's understanding of fertility, pregnancy, and early risk factors for childhood and adult diseases. The long-term goals of the research are to learn how to better understand, prevent, diagnose or treat conditions like infertility, intrauterine growth restriction (or IUGR), childhood diabetes, and high blood pressure. It is not possible to list every research project. Also, we cannot predict all of the research questions that will be important in the coming years. The more we learn, the better able we will be to ask important questions about environmental exposures during the pre-pregnancy period.

Your samples and information may also be used for research on other conditions; for example, as comparisons to other diseases. This could include a wide variety of conditions such as mental illness, HIV/AIDS, cancer, and others as described in your electronic medical records. We will not be conducting diagnostic tests.

We plan to do genetic research on the DNA in your biological sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the parts of cells that contain the instructions that tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

Your biological sample may be used to create a living biological sample (called a "cell line") that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

We also may perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links between environmental exposures and both childhood and adult diseases.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. The sample/data banks provide study data for researchers working on any disease.

The research we are doing is only a stepping stone in understanding some of the predictors of fertility and origins of maternal and child disease and is not being done for the purpose of individual diagnosis. Therefore, information from this research will not be returned to you or your doctor. Tests done for research using your samples will not be useful in directing your medical treatment. This information will not be placed in your medical records. However if there is anything that is clinically relevant we will notify you.

Staff at the biobank will assign your sample a code number and store it in a freezer. They will not keep your name or other information that could identify you with your sample. They will use the code number to connect your sample to your health information that is stored in a secure computer database. The computer database is protected with a password. Only staff at the biobank will know the password.

There is no scheduled date on which your samples and information in the biobank will be destroyed. Your samples may be stored for research until they are “used up.”

The code linking your samples to your medical record may be kept indefinitely so that your samples and updated health information may be used for research in the future.

You have a right to withdraw your permission at any time. If you do, your samples and your information will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers. If you decide to withdraw your permission, you should contact the biobank’s staff in writing: *Dr. Leonardo Trasande, MD, NYU School of Medicine, 403 East 34th Street, Room 100, New York, NY 10016.*

5. What are the possible risks or discomforts?

There is a small risk of bruising and soreness from having blood drawn and a small risk of discomfort from the vaginal and rectal swabs.

There is also a potential risk of loss of privacy from allowing us to store and use your samples and certain limited health information for research. We will make every effort to protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password-protected database.

As part of the study we would like to analyze some samples for genetic markers that may be associated with fertility, pregnancy complications, and some common childhood diseases. The genetic information that results from this study does not have medical or treatment importance at this time and is protected with encryption. Further, the results of genetic testing will not be shared with you, your medical providers, or your insurance provider.

6. What if new information becomes available?

During the course of this study, we may discover information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

You will not directly benefit from research conducted on your samples stored in the research biobank. We hope that research using the samples and information you provide will help us understand, prevent, treat, or cure the illnesses and conditions studied.

8. What other choices do I have if I do not participate?

If you would prefer not to participate in this study, please know that it is your right to do so and that this will in no way impact the care you receive.

9. Will I be paid for being in this study?

You will not be paid for participating in this study, but you will receive a detailed report of your body composition, and a box of 25 pregnancy test strips every 5 months.

10. Will I have to pay for anything?

There is no cost to you for your clinic visit or follow-up contacts, for having your samples stored in the biobank, or for the research conducted using your samples.

11. What happens if I am injured from being in the study?

If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYULMC or NYU SoM to pay you or give you other compensation for the injury. However, you do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the study before it ends?

This study is expected to continue indefinitely. However, your involvement will end when you either become pregnant, or stop trying to become pregnant. If you conceive and are not planning to deliver at an NYU-affiliated hospital, we will contact you approximately 5 months later to check on your pregnancy status.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your healthcare, or your eligibility for healthcare benefits.

13. How will my information be protected?

NYU Langone Medical Center, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

The following information may be used or shared in connection with this research:

- Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, and questionnaires.

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Medical Center policies and applicable law.

Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

The following individuals may use, share, or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

14. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies, including this study. The IRB follows federal government rules and guidelines designed to protect the rights and welfare of people taking part in research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYULMC IRB Office number is (212) 263-4110. The NYULMC IRB is made up of doctors, nurses, non-scientists, and people from the community.

15. Who can I call with questions or if I'm concerned about my rights as a research subject?

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)

Signature of Subject

Date

Name of Person Obtaining Consent
(Print)

Signature of Person Obtaining Consent

Date

Witness to Consent of Non-English Speaking Subjects Using the “Short Form” in Subject’s Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date
-------------------------	----------------------	------

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- Subject making his/her own “X” above in the subject signature line
- Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date
-------------------------	----------------------	------