# CONSENT FORM

**Title of Research Project: Longitudinal Investigation of Fertility and the Environment Study (LIFE Study)**

**Principal Investigator: Timothy Wilcosky, PhD**

## Introduction

The Longitudinal Investigation of Fertility and the Environment (LIFE) Study is a research study conducted by RTI International and sponsored by the National Institute of Child Health and Human Development. We are working with researchers from Johns Hopkins University in Maryland and Texas A&M University. This consent form explains the study you are being asked to join.

## Purpose of Research Project:

The LIFE Study is trying to find out if exposures to some types of chemicals in the environment might make it harder for couples to have a baby. We will measure these chemicals in blood and urine from the study couples, and we will see if a longer time is needed to get pregnant when a woman or man has high levels of these chemicals. The study will also look for associations of these chemicals with infertility, pregnancy loss, length of gestational period, and infant birth size.

You have been asked to participate in the study because either you or your partner live in Berrien or Ingham Counties in Michigan, where the study is taking place. To participate, you must be between the ages of 18 and 40 years old, and you and your partner must be planning to try to become pregnant. About 250 couples will participate.

## Participation:

Your participation in this study is completely voluntary, and if you do join, you can withdraw at any time. Because we are enrolling couples, both you and your partner must agree to participate. If either of you decides to withdraw at anytime during the study, then both of you will end your participation in the study. If you and your partner change your mind about trying to have a child, you will not need to continue in the study. We may ask your permission to contact you again in the future to see if you have started trying again to have a child.

## Procedures:

You will be asked to donate various biological samples. These include one 23 ml (about 1 ½ tablespoons) sample of blood, 3 samples of urine totaling about 8 ounces (1 cup), and 2 saliva samples. You will also be asked to answer a questionnaire at the beginning of the study, as well as fill out a brief daily journal while trying to become pregnant. If you become pregnant, you will be asked to fill out a weekly journal throughout your pregnancy. Your participation in the study could range from 9 to 21 months depending on whether or not you become pregnant and on the course of the pregnancy.

A study staff person will visit your home at least 3 times. During the first visit, you will be asked to complete the initial questionnaire, which should take about 30 minutes. This questionnaire will collect information about your job history, medical history, gynecologic history, reproductive history, family health history, and lifestyle. After the interview, we will measure your weight, height, and waist and hip size, which will take about 2 minutes.

You will also be trained to use an electronic fertility monitor, a pregnancy test kit, and a daily journal. The daily journal will ask for information about your lifestyle, reproductive habits, and menstrual cycles; the questions should take you about 3-5 minutes each day to complete. You can either mail in the journal each week at no cost to you or complete it using the Internet if you have a suitable home computer. The choice is yours. You will be taught how to collect saliva samples and mail them to a study laboratory; this collection will happen 2 different times.

At the end of the first visit, a trained nurse will draw a blood sample and ask you to provide a urine sample. A pregnancy test will be performed using the urine sample to ensure that you are not currently pregnant. The entire first visit should take about 1 hour. On the second visit about one month later, you will be asked to provide another sample of urine. Staff members will also review the use of the fertility monitor and pregnancy test kit with you.

Additional home visits might occur to permit the staff to review the training, bring supplies, and to collect the fertility monitor information. These visits will be much shorter than the first visit (about 20-30 minutes).

If you have a positive pregnancy test, staff members will make another visit. During this visit, you will be asked to give a final urine sample, and will be instructed on how to fill out a short weekly journal during the course of your pregnancy. The completion of this journal should take 3-5 minutes each week, and you will be asked to mail in the diary cards at no cost to yourself or enter the information over the Internet. This journal, like the previous one, will collect information about your lifestyle and reproductive habits and general health during pregnancy. Fertility monitor information will be collected during this visit by staff and you will receive an incentive for your participation. After the baby is born, you will be asked to provide information about birth size. This information will be collected in the final follow-up visit, when you will also receive a completion gift.

If you have been enrolled in the study for 6 months, and have not become pregnant, you will then be asked to provide another sample of urine.

Your name will be placed on file at the research site to allow for recruitment for future studies, unless you decide now or at any other time during the study, to refuse. Please check one of the following options about your wishes to have your name kept on file:

______ I do not want my name to be kept on file for future study recruitment.
______ I will allow my name to be kept on file for future study recruitment.

Your biological samples will also be kept in storage for future analysis, possibly related to other studies (for example, studies of other chemical exposures), unless you decide now or at any other time during this study to refuse. No genetic material will be kept. Please check one of the following options about your wishes to have your samples stored:

_____ I do not wish to have my samples stored and used for future studies.
_____ I will allow my samples to be stored and used for future studies.

**Risks/Discomforts**:
Some people experience bruising and /or slight discomfort during and after the blood draws.

This study will ask you to discuss personal sensitive information. Some people may find this difficult or embarrassing. You have the right to refuse to answer any question or to refuse any part of the study. Also, you may gain knowledge about your own or your partner's fertility that you did not expect. Some people may find this knowledge uncomfortable or embarrassing.

There is a very small risk of sensitive personal information being passed along to people outside the study. However, the Confidentiality section below describes the measures being taken by the study staff to make that risk as small as possible.

**Benefits:**
There will be no direct benefit to you or your partner if you agree to participate in this research project. However, you may gain a better understanding of your own fertility and reproductive cycles. There may be benefit to other couples in the future that are trying to become pregnant.

**Confidentiality:**
Research staff will do their best to protect your personal privacy and the confidentiality of your information. Interviews will be done in a private setting and specimens will be collected at home. Specimens will be labeled only with an ID number. Only the researchers at the site that enrolled you will be able to link your ID number with your name, and will be able to contact you. You will be given a unique code that is used when submitting your journal entries and specimens. No personal identifiers other than your birth date are stored in the study's central computer system. If you decide to submit journal entries over the Internet, that information will not include personal identifiers and will be unreadable by others who are not part of the research study. Despite these precautions, total privacy cannot be guaranteed.

The study researchers might voluntarily disclose your identity if it is necessary to protect you or others from serious harm, such as situations of child abuse, possible threat to self or others, or high levels of toxic chemicals in the environment (for example, lead exposure).

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The Certificate will protect researchers from being forced to disclose information that may identify you. 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.

In general, findings from this study may increase scientific understanding of environmental exposures and how they may affect human reproduction or development. Only non-identifying information from many couples will be used in publications or released for study by other research investigators.

**Compensation:**
You will receive payment for giving biological samples during home visits according to the following schedule. During the 1st visit, you will receive a total of $30: $25 for blood and $5 for urine. During the 2nd visit, you will receive a total of $25: $20 for saliva samples that have been received and $5 for urine. During the next visit, you will be given $20 for any saliva samples that have been received by the study staff. If a urine sample is collected during pregnancy, you will be given $5 when the sample is received. During the 1st visit after pregnancy has occurred, the couple will receive a pregnancy related book and after the birth of your baby, the couple will receive a baby gift. Couples who do not conceive during 12 cycles of attempting to become pregnant will receive a gift at the end of that time period.

All fertility monitors, monitor test sticks, pregnancy kits, journals, and shipping materials will be provided at no cost to you. You may keep the fertility monitor and unused monitor test sticks and pregnancy test kits after completing the study.

**For additional information:**
If you have questions about the study, you should call the principal investigator, Timothy Wilcosky, PhD, toll-free at 1-800-334-8571, extension 7367.
If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

**Signature that indicates consent:**
Your signature below tells us that you understand the purposes and steps of the study, and that you agree to take part in the study. Please return the top copy of this form. The second copy is yours to keep.

Print Name of Subject:________________________________________

____________________________________ ____________

Signature or Mark of Subject or Legally Authorized Representative | Date

Signature of Person Obtaining Consent — Date

Witness to Consent if Subject Unable to Read or Write — Date
*(Must be different than the person obtaining consent)*

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A study staff person will visit your home at least 3 times. During the first visit, you will be asked to complete the initial questionnaire, which should take about 30 minutes to finish. This questionnaire will collect information about your job history, medical history, reproductive history, family health history, and lifestyle. After the interview, we will measure your weight, height, and waist and hip size, which will take about 2 minutes.

The daily journal will ask for information about your lifestyle and reproductive habits. The questions should take you about 3-5 minutes each day to complete. You can either mail in the journal each week at no cost to you or complete it using the Internet if you have a suitable home computer. The choice is yours. You will be taught how to collect semen samples and mail them to a study laboratory; this collection will happen 2 different times.

At the end of the first visit, a trained nurse will draw a blood sample and ask you to provide a urine sample. The entire first visit should take about 1 hour. A semen collection kit will be left with you at your home. You will be asked to collect one semen specimen after 2 days of abstinence from ejaculation and send it to the laboratory in the prepaid Federal Express packaging. On the second visit about one month later, you will be asked to provide another sample of urine. Following that visit you will collect a second semen sample after 2 days of abstinence and send it to the laboratory.

Additional home visits will occur to permit the staff to review the training, bring supplies, and to collect your partner's monitor information. These visits will be much shorter than the first visit (about 20-30 minutes).

If your partner has a positive pregnancy test, staff members will make another visit. Your partner will be asked to provide another urine sample and will be instructed in completing a journal during pregnancy. Fertility monitor information will be collected during this visit by staff and your partner will receive an incentive for her participation. After the baby is born, your partner will be asked to provide information about birth size. This information will be collected in the final follow up visit, when a completion gift will also be presented to your partner.

Your name will be placed on file at the research site to allow for recruitment for future studies, unless you decide now or at any other time during the study, to refuse. Please check one of the following options about your wishes to have your name kept on file:

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To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The Certificate will protect researchers from being forced to disclose information that may identify you. 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.

In general, findings from this study may increase scientific understanding of environmental exposures and how they may affect human reproduction or development. Only non-identifying information from many couples will be used in publications or released for study by other research investigators.

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____________________________________ ____________
Signature or Mark of Subject or Legally Authorized Representative — Date

____________________________________ ____________
Signature of Person Obtaining Consent — Date

____________________________________ ____________
Witness to Consent if Subject Unable to Read or Write — Date
*(Must be different than the person obtaining consent)*