Longitudinal Investigation of Fertility and the Environment Study (LIFE Study)

FEMALE CONSENT FORM

Introduction

The Longitudinal Investigation of Fertility and the Environment (LIFE) Study is a research study being conducted by Texas A&M System Health Science Center's School of Rural Public Health and is sponsored by the National Institute of Child Health and Human Development. Researchers from Johns Hopkins University in Maryland and Research Triangle Institute in North Carolina are working together with the School of Rural Public Health in this study. This consent form explains the research study I am being asked to join. I will review this form carefully and ask any questions about the study before I agree to join. I may also ask questions at any time after joining the study.

Purpose of Research Project:

The LIFE Study is trying to find out if exposures to some types of chemicals found in the environment might make it harder for couples to have a baby. Chemicals will be measured in blood and urine from the study couples, and will be used to see if a longer time is needed to get pregnant when a woman or man has higher levels of these chemicals. The study will also look for associations of these chemicals to infertility, pregnancy loss, length of gestational period, and infant birth size. The study will take into account lifestyle factors that could potentially influence the results.

Couples in this area and the other 2 study areas will meet the following requirements:
1. The woman is between the ages of 18 and 40 years
2. The man is between the ages of 18 and 60 years
3. Neither partner has been surgically sterilized
4. Neither partner has a known medical condition that could result in infertility
5. The couple resides in a geographic area of interest to the study
6. The couple is ready to attempt to become pregnant in the next 3 to 6 months

It is anticipated that a total of 800 couples will participate in this study across the three different geographic locations.

The study is funded by the federal government, through the National Institute for Child Health and Human Development, which is part of the National Institutes of Health.

Procedures:

I have been asked to participate in this study because either I or my partner are in the Texas Parks and Wildlife Department's Angler database and I am a female between the ages of 18 and 40 years. My partner and I are either planning to stop any current contraception within the next 6 months, or have not used any method of birth control for the past two months, and are planning on actively trying to become pregnant. Neither I, nor my partner, have been diagnosed with any infertility problems and we can both communicate in English, Spanish, or Vietnamese.

By agreeing to participate in this study, I understand that I 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, or one cup, and 2 saliva samples. I 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 and during the first 4 weeks of pregnancy. Pregnant women will then be asked to fill out a weekly journal throughout the remainder of pregnancy. I will be visited multiple times at my home as outlined in the following paragraphs. The entire duration of my and my partner's participation from enrollment to completion of the study could range from 9 to 21 months depending on whether or not I become pregnant and the course of the pregnancy.

During the first visit, I will be asked to complete the initial questionnaire, which should require approximately 30 minutes to finish. This questionnaire will collect information regarding my job history, medical history, gynecologic history, reproductive history, family health history, lifestyle factors, and demographic information. Following the interview, body size measurements will be taken, including your weight, height and waist and hip circumferences, requiring approximately 2 minutes of your time.

I will also be trained in how to use an electronic fertility monitor, pregnancy tests and daily journals. The daily journals will ask for information about my lifestyle characteristics, reproductive habits, and menstrual cycles. It should take about 3-5 minutes of my time each day. These journals can either be mailed in each week at no cost to myself or completed using the Internet if I have a suitable home computer. The choice is mine. I will be taught how to collect a saliva sample at a later date and how to mail it back to study staff. This collection will occur at 2 different times in the future.

At the end of the first visit, I will be asked to provide samples of both blood and urine. A blood sample will be drawn by an individual trained in this procedure. A pregnancy test will be performed using the urine sample to ensure that I am not currently pregnant. The entire initial visit should require about 1 hour of your time.

On the second visit, I 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 me.

Additional home visits will occur to permit the staff to review the training, bring supplies, give compensation for donating the samples, and to collect the monitor information. These visits will be much shorter in duration than the initial visit, requiring approximately 20-30 minutes to complete.

If and when I have a positive pregnancy test, staff members will make another visit. During this visit, I 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 my pregnancy. The completion of this journal should take 3-5 minutes each day and I will be asked to mail in the diary card once a month at no cost to myself or enter the information over the Internet. This journal, like the previous one, will collect information about my lifestyle and

reproductive habits and general health during pregnancy. Fertility monitor information will be collected during this visit by staff and an incentive will be given at this stage of the study. After the baby is born, I will be asked to provide information about pregnancy outcomes. This information will be collected in the final follow up visit, when a completion gift will also be presented to me.

If I have been enrolled in the study for 6 months, and have not become pregnant, I will then be asked to provide a final sample of urine. I will continue with my participation in the study in the same way as before until 12 months have passed, or I become pregnant and have delivered.

My name will be placed on file at the research site to allow for recruitment for future studies, unless I decide now or at any other time during the study, to refuse. I have checked one of the following options about my wishes to have my 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.

My biological samples will also be kept in storage for future analysis, possibly related to other studies, unless I decide now or at any other time during this study, to refuse. I have checked one of the following options about my wishes to have my 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:
There are few physical risks or discomforts that are possible with my participation. I will be asked to provide a blood sample and some people do experience bruising and /or slight discomfort during and after the blood draws.

This study will ask me to discuss personal sensitive information. Some people may find this difficult or embarrassing. I do not have to answer any questions that I am uncomfortable answering. As a result of participating in this research, 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 risk of sensitive personal information being passed along to those 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 me or my partner if I agree to participate in this research project. However, I may gain a better understanding of my own fertility and reproductive cycles. There may be benefit to other couples in the future who are trying to become pregnant.

Alternatives for Participation:
I may decline to participate in any portion of the study at any time during the study. By choosing not to be a part of the study, I have the option of attempting to become pregnant outside the study either with or without the aid of a commercially available fertility monitor as used in this study. Any supportive information on pregnancy found on the study web site is accessible to the general public.

Confidentiality:
Research staff will do their best to protect my personal privacy and the confidentiality of my information. Interviews will be done in a private setting and specimens will be collected at home. Maintaining my privacy depends on protecting personal identifiers such as my name, address and telephone number. Only the researchers at the site that enrolled me know my personal identifiers and will be able to contact me. I will be given a unique code that is used when submitting my journal entries and specimens. No personal identifiers other than my birth date are stored in the study's central computer system. If I 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.

Every effort will be made to protect the confidentiality of the information provided insofar as it is legally possible. Under certain conditions, people in charge of making sure that the research is done properly may review my study records. This might include people from the local institutional review board and the Federal Office for Human Research Protections. All of these people are also required to keep my identity confidential.

The study researchers might voluntarily disclose your identify if it is necessary to protect me or others from serious harm. It might be necessary to reveal my identity in situations of child abuse, reportable communicable diseases, possible threat to self or others, or reportable levels of toxic chemicals in the environment (for example, lead exposure).

To help protect my privacy, a Certificate of Confidentiality from the National Institutes of Health has been obtained. With this Certificate, the researchers cannot be forced to disclose information that may identify me, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify me, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects.

I understand that a Certificate of Confidentiality does not prevent me or a member of my family from voluntarily releasing information about me or my involvement in this research. If a physician, insurer or other person gets my written permission/approval to

receive research information, 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 effect 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:
I will receive payment for giving biological samples during home visits according to the following schedule. During the 1st visit, I will receive a total of $30: $25 for blood and $5 for urine. During the 2nd visit, I will receive a total of $25: $20 for saliva samples that have been received and $5 for urine. During any additional visits, I will be given $20 for any saliva samples that have been received by the study staff. If a urine sample is collected during pregnancy, I will be given $5 when the sample is received. During the 1st visit after pregnancy has occurred, my partner and I will receive a pregnancy related book and after the birth of my baby, we 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 12 at-risk cycles.

All fertility monitors, monitor test sticks, pregnancy kits, journals and courier charges or mail postage will be provided at no cost to myself. The fertility monitor and unused monitor test sticks and pregnancy test kits will remain in the hands me and my partner upon our completion of the study.

Voluntariness:
My participation in this research project is completely voluntary. I have the right to withdraw from the research study at any time. I should ask the principal investigator listed below any questions you may have about this research study. I may ask him/her questions in the future if you do not understand something that is being done.

Persons to Contact:
If I want to talk to anyone about this research study because I think I have not been treated fairly or think I have been hurt by joining the study, or I have any other questions about the study, I should call the principal investigator, Anne M. Sweeney, PhD by phone at (979) 458-0068 or email at amsweeney@srph.tamushsc.edu. I may also contact one of Anne's research associates, Cortney Ferguson, MPH by phone at (979) 458-2809 or email at cgferguson@srph.tamushsc.edu.

This research study has been reviewed by the Institutional Review Board-Human Subjects in Research, Texas A&M University. For research-related problems or questions regarding subjects' rights, I can contact the Institutional Review Board through Dr. Michael W. Buckley, Director of Research Compliance, Office of Vice President for Research at (979) 845-8585 (mwbuckley@tamu.edu).

Texas A&M System Health Science Center's School of Rural Public Health and the Federal government do not have any program to provide compensation to I if you experience injury or other bad effects which are not the fault of the investigators.

If I have read this document and I have been given the chance to ask any questions now or at a later time or if the document has been read and explained to me and I agree to be in this study, please sign or make your mark below. I will be given a copy of this consent form to keep for my records.

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 *(Must be different than the person obtaining consent)*	Date

Longitudinal Investigation of Fertility and the Environment Study (LIFE Study)

MALE CONSENT FORM

Introduction
The Longitudinal Investigation of Fertility and the Environment (LIFE) Study is a research study conducted by Texas A&M System Health Science Center's School of Rural Public Health and is sponsored by the National Institute of Child Health and Human Development. Researchers from Johns Hopkins University in Maryland and Research Triangle Institute in North Carolina are working with the School of Rural Public Health in this study. This consent form explains the research study I am being asked to join. I will review this form carefully and ask any questions about the study before I agree to join. I may also ask questions at any time after joining the study.

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Couples in this area and the other 2 study areas will meet the following requirements:
1. The woman is between the ages of 18 and 40 years
2. The man is between the ages of 18 and 60 years
3. Neither partner has been surgically sterilized
4. Neither partner has a known medical condition that could result in infertility
5. The couple resides in a geographic area of interest to the study
6. The couple is ready to attempt to become pregnant in the next 3 to 6 months

It is anticipated that a total of 800 couples will participate in this study across the three different geographic locations.

The study is funded by the federal government, through the National Institute for Child Health and Human Development, which is part of the National Institutes of Health.

Procedures:
I have been asked to participate in this study because either I or my partner are in the Texas Parks and Wildlife Department's Angler database and I am a male of at least 18 years of age. My partner and I are either planning to stop any current contraception within the next 6 months, or have not used any method of birth control for the past two months, and are planning on actively trying to become pregnant. Neither I nor, my partner, have been diagnosed with any infertility problems and we can both communicate in English, Spanish, or Vietnamese.

By agreeing to participate in this study, I understand that I will be asked to donate various biological samples. These include one 23 ml (about 1 ½ tablespoons) sample of blood, 2 samples of urine totaling about 8 ounces, or one cup, and 2 semen samples. I will also be asked to answer a questionnaire at the beginning of the study, as well as fill out a brief daily journal while my partner is trying to become pregnant. I will be visited multiple times at my home as outlined in the following paragraphs. The entire duration of my and my partner's participation from enrollment to completion of the study could range from 9 to 21 months depending on whether or not my partner becomes pregnant and the course of the pregnancy.

During the first visit, I will be asked to complete the initial questionnaire, which should require approximately 30 minutes to finish. This questionnaire will collect information regarding my job history, medical history, reproductive history, family health history, lifestyle factors, and demographic information. Following the interview, body size measurements will be taken, including my weight, height and waist and hip circumferences, requiring approximately 2 minutes of your time.

The daily journal will ask for information about my lifestyle characteristics and reproductive habits. It should take about 3-5 minutes of my time each day. These journals can either be mailed in each week at no cost to myself or completed using the Internet if I have a suitable home computer. The choice is mine. I will be taught how to collect a semen sample and how to send it back to the laboratory. This collection will occur one more time in the future.

At the end of the first visit, I will be asked to provide samples of both blood and urine. A blood sample will be drawn by an individual trained in this procedure. The entire initial visit should require about 1 hour of my time. Two semen collection kits will be left with me and I will collect one semen specimen after 2 days of abstinence from ejaculation. The kit will be returned to the laboratory in the provided packaging by Fedex courier.

On the second visit, I will be asked to provide another sample of urine. Following that visit, I will collect a second semen sample after 2 days of abstinence and send it to the laboratory. Collection of this sample will be timed to occur during my partner's menses, when fertility would be low.

Additional home visits will occur to permit the staff to review the training, bring supplies, give compensation for donating the samples, and to collect my partner's monitor information. These visits will be much shorter in duration than the initial visit, requiring approximately 20-30 minutes to complete.

If and when my partner has a positive pregnancy test, staff members will make another visit. My 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 an incentive will be given at this stage of the study. I will not be asked for further samples on these visits and my journal entries will not continue after your partner is pregnant. After the baby is born, my 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 my partner.

Participation in the study will continue until 12 months have passed, or my partner becomes pregnant and has delivered.

My name will be placed on file at the research site to allow for recruitment for future studies, unless I decide now or at any other time during the study, to refuse. I have checked one of the following options about my wishes to have my 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.

My biological samples will also be kept in storage for future analysis, possibly related to other studies, unless I decide now or at any other time during this study, to refuse. 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:
There are few physical risks or discomforts that are possible with my participation. I will be asked to provide a blood sample and some people do experience bruising and /or slight discomfort during and after the blood draws.

This study will ask me to discuss personal sensitive information. Some people may find this difficult or embarrassing. I do not have to answer any questions that I am uncomfortable answering. As a result of participating in this research, I may gain knowledge about my own or my partner's fertility that you did not expect. Some people may find this knowledge uncomfortable or embarrassing.

There is a risk of sensitive personal information being passed along to those 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 me or my partner if I agree to participate in this research project. However, I may gain a better understanding of my own fertility. There may be benefit to other couples in the future who are trying to become pregnant.

Alternatives for Participation: I may decline to participate in any portion of the study at any time during the study. By choosing not to be a part of the study, I have the option of attempting to father a pregnancy with my partner outside the study either with or without the aid of a commercially available fertility monitor as used in this study. Any supportive information on pregnancy found on the study web site is accessible to the general public.

Confidentiality:
Research staff will do their best to protect my personal privacy and the confidentiality of my information. Interviews will be done in a private setting and specimens will be collected at home. Maintaining my privacy depends on protecting personal identifiers such as my name, address and telephone number. Only the researchers at the site that enrolled me know my personal identifiers and will be able to contact me. I will be given a unique code that is used when submitting my journal entries and specimens. No personal identifiers other than my birth date are stored in the study's central computer system. If I 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.

Every effort will be made to protect the confidentiality of the information provided insofar as it is legally possible. Under certain conditions, people in charge of making sure that the research is done properly may review my study records. This might include people from the local institutional review board and the Federal Office for Human Research Protections. All of these people are also required to keep my identity confidential.

The study researchers might voluntarily disclose my identify if it is necessary to protect me or others from serious harm. It might be necessary to reveal my identity in situations of child abuse, reportable communicable diseases, possible threat to self or others, or reportable levels of toxic chemicals in the environment (for example, lead exposure).

To help protect my privacy, a Certificate of Confidentiality from the National Institutes of Health has been obtained. With this Certificate, the researchers cannot be forced to disclose information that may identify me, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify me, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects.

I understand that a Certificate of Confidentiality does not prevent me or a member of my family from voluntarily releasing information about yourself or your involvement in this research. If a physician, insurer or other person gets my written permission/approval to receive research information, 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 effect 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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I will receive payment for giving biological samples during home visits according to the following schedule. During the 1st visit, I will receive a total of $30: $25 for blood and $5 for urine. During the 2nd visit, I will receive a total of $25: $20 for one semen sample that has been received and $5 for urine. During the next visit, I will be given $20 for the second semen sample that has been received by the study staff. During the 1st visit after pregnancy has occurred, my partner and I will receive a pregnancy related book and after the birth of my baby, we 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 12 at-risk cycles.

All fertility monitors, monitor test sticks, pregnancy kits, journals and courier charges or mail postage used in this study will be provided at no cost to myself. The fertility monitor and unused monitor test sticks and pregnancy test kits will remain in the hands of the couple upon their completion of the study.

Voluntariness:
My participation in this research project is completely voluntary. I have the right to withdraw from the research study at any time. I should ask the principal investigator listed below any questions you may have about this research study. I may ask him/her questions in the future if I do not understand something that is being done.

Persons to Contact:
If I want to talk to anyone about this research study because I think I have not been treated fairly or think I have been hurt by joining the study, or I have any other questions about the study, I should call the principal investigator, Anne Sweeney, PhD at (979) 458-0068 or by email amsweeney@srph.tamushsc.edu. I may also contact one of Anne's research associates, Cortney Ferguson, MPH by phone at (979) 458-2809 or by email at cgferguson@srph.tamushsc.edu.

This research study has been reviewed by the Institutional Review Board-Human Subjects in Research, Texas A&M University. For research-related problems or questions regarding subjects' rights, I can contact the Institutional Review Board through Dr. Michael W. Buckley, Director of Research Compliance, Office of Vice President for Research at (979) 845-8585 (mwbuckley@tamu.edu).

Texas A&M System Health Science System's School of Rural Public Health and the Federal government do not have any program to provide compensation to you if you experience injury or other bad effects which are not the fault of the investigators.

If I have read this document and have been given the chance to ask any questions now or at a later time or if the document has been read and explained to me and I agree to be in this study, please sign or make your mark below. I will be given a copy of the signed consent form to keep for my records.

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 *(Must be different than the person obtaining consent)*	Date