

**LIFE Study Screening Questionnaire
Selected Male with Female Partner Version**

Q1. Hello, my name is _____, and I am calling from _____. I am trying to reach (selected man's first and last name) about an important health-related study that we are conducting. May I please speak with him

- If unavailable (Proceed to Q2) 1
- If speaking (Skip to Q3) 2
- If available (Skip to Q3a) 3

- Wrong number (Thank and end call) 8
- Refused (Probe for reason, thank and end call) 9
- Reason for refusal: _____

Q2. Could you please tell me when would be a good time to reach him?

- Indicate day/time (Thank and end call): _____
- Refused (Thank and end call) 9
- Reason for refusal: _____

Q3. (If selected man is speaking) As I mentioned, I am calling from _____, and we are contacting (anglers/men) in the area to see if they would be interested in participating in a study about how the environment might affect a couple's ability to have a baby. To help me determine if you are eligible to participate in this important project, I'd like to ask you a few questions. This short interview will take about 5 to 10 minutes to complete. Is now a good time for you?

- No 0
- Yes 1

- Refused (Thank and end call) 9
- Reason for refusal: _____

Q3a. (When selected man comes to the phone) Hello, my name is _____, and I am calling from _____. We are contacting (anglers/men) in the _____ area to see if they would be interested in participating in a study about how the environment might affect a couple's ability to have a baby. To help me determine if you are eligible to participate in this important project, I'd like to ask you a few questions. This short interview will take about 5 to 10 minutes to complete. Is now a good time for you?

- No 0
- Yes 1

- Refused (Thank and end call) 9
- Reason for refusal: _____

Q4. I'd like to schedule a time to call you back to complete the short interview. What is the best time to reach you?

Specify day/time: _____ (Thank and terminate)

9999 Refused (Probe for reason, thank and terminate)

Reason: _____

Q5. Before I begin, I would like to take a moment to provide you with some additional information about the interview.

(Read informed consent passage – see Appendix A, Male Consent Passage)

Do you have any questions?

0 No (Continue to Q6)

1 Yes (Answer questions, verify that respondent understands answers, and continue to Q6)

Q6. By agreeing to participate in this interview, you are indicating that:

- You have had the purpose of the interview explained to you;
- You have had the risks and benefits of participation explained to you;
- You have had the opportunity to ask questions about things that you did not understand;
- You willingly give your consent to voluntarily participate.

Are you willing to participate in this short interview?

0 No (Probe for reason, thank and terminate)

Reason: _____

1 Yes (Continue to Q7)

Q7. Are you at least 18 years of age?

0 No (Thank and terminate)

1 Yes (Continue to Q8)

If 0 in Q7: Inform respondent that we are only enrolling men aged 18 years or older.

Q8. Do you have a wife or female partner with whom you have a committed relationship?

0 No (Thank and terminate)

1 Yes (Continue to Q9)

If 0 in Q8: Inform respondent that we are only enrolling couples. If your situation changes and you would like to learn more about the study, please call us at XXX-XXX-XXXX.

Q9. Is your wife or partner between the ages of 18 and 40 years old?

- 0 No (Thank and terminate.)
- 1 Yes (Continue to Q10)

Q10. Which of the following best describes your current marital status? Are you (read 1-4)?

- 1 Married
- 2 Single, but living as a couple
- 3 Single, not living as a couple
- 4 Divorced/widowed/separated

Q11. Have you ever been told by a doctor that it would be impossible for you to father a child without medical help?

- 0 No (Skip to transition statement before Q13)
- 1 Told that "it might be difficult" (Continue to Q12)
- 2 Yes (Continue to Q12)

- 8 Don't know (Obtain contact information and follow-up in one week)

Q12. Is this because you have had a vasectomy, sometimes called a V-section or having your tubes tied, or is there some other reason?

- 1 Vasectomy (Probe to see if reversed. If yes, continue. If no, thank and terminate.)
- 2 Some other reason
Specify: _____
(Thank and terminate. This response should be reviewed by a supervisor for possible eligibility and the woman should be re-contacted as appropriate.)

Q13. Based on your answers, you may be eligible to participate in an important research project called the LIFE Study. Since we are enrolling couples in this study, may I please speak to your wife/partner so that I may ask her a few questions to help me determine if she is also eligible for participation?

- 0 Not available (Continue)
- 1 Available (Skip to Q15)

- 9 Refused (Probe for reason, thank and terminate)
Reason: _____

Q14. Can you please tell me your wife/partner's name and when would be a good time to reach her?

Specify name: _____
Specify day/time: _____ (Thank and terminate)

- 9999 Refused (Probe for reason, thank and terminate)
Reason: _____

Q15. (When wife/partner is reached) Hello, my name is _____, and I am calling from _____ . We are contacting couples in the _____ area to see if they would be interested in participating in a study about how the environment might affect a couple's ability to have a baby. To help me determine if you are eligible to participate in this important project, I'd like to ask you a few questions. This short interview will take about 5 to 10 minutes to complete. Is now a good time for you?

- No0
- Yes1

- Refused (Thank and end call).....9
- Reason for refusal:_____

Q16. I'd like to schedule a time to call you back to complete the short interview. What is the best time to reach you?

- Specify day/time: _____ (Thank and terminate)

- 9999 Refused (Probe for reason, thank and terminate)
- Reason: _____

Q17. Before I begin, I would like to take a moment to provide you with some additional information about the interview.

(Read informed consent passage – see Appendix B, Female Consent Passage)

Do you have any questions?

- 0 No (Continue to Q18)
- 1 Yes (Answer questions, verify that respondent understands answers, and continue to Q18)

Q18. By agreeing to participate in this interview, you are indicating that:

- You have had the purpose of the interview explained to you;
- You have had the risks and benefits of participation explained to you;
- You have had the opportunity to ask questions about things that you did not understand;
- You willingly give your consent to voluntarily participate.

Are you willing to participate in this short interview?

- 0 No (Probe for reason, thank and terminate)
- Reason: _____
- 1 Yes (Continue to Q19)

Q19. Are you currently pregnant?

- 0 No (Continue)
- 1 Yes (Thank and terminate)

- 8 Don't know (Obtain contact information and follow-up in one week.)

If Q19=1: Inform respondent that we are currently seeking couples that are thinking about trying to have a baby, rather than those that are already pregnant.

Q20. Have you ever been told by a doctor that it would be impossible for you to get pregnant without medical help?

- 0 No (Skip to Q22)
- 1 Yes (Continue to Q21)

- 8 Respondent was advised by a doctor not to get pregnant
Reason: _____
(Thank and terminate. This response should be reviewed by a supervisor for possible eligibility and the woman should be re-contacted as appropriate.)

Q21. Which of the following reasons best describes why it would be impossible for you to get pregnant without medical help? If there is more than one reason, please indicate all that apply.

- 1 Your uterus (womb) is missing or has been removed (Thank and terminate)
- 2 Both of your ovaries are missing or have been removed (Thank and terminate)
- 3 Both of your fallopian tubes are missing or have been removed
(Thank and terminate)
- 4 You have had a tubal sterilization (i.e., tubes tied, clamped, etc.)
(Probe to see if reversed. If yes, continue. Otherwise, thank and terminate.)
- 5 Some other reason
Specify: _____
(Thank and terminate. This response should be reviewed by a supervisor for possible eligibility and the woman should be re-contacted as appropriate.)

Q22. In the 12 months, how many days on average have there been between the start of one menstrual period (first day of bleeding) and the next menstrual period (first day of bleeding)?

- 0 Have not had a period in the past 12 months
- 1-365 Specify days (Probe for approximate number of days)
- 999 Too irregular to know

If Q22=0 or Q22 (<21 or >42 days) or Q22=999 then thank and terminate (Inform respondent that we are only enrolling women with menstrual cycles that are typically 21 to 41 days long). Otherwise, continue.

The last few questions relate to birth control use and your feelings about becoming pregnant.

Q23. Which of the following statements best describes your current feelings about becoming pregnant?

- 1 I am open to becoming pregnant at any time (Continue)
- 2 I don't wish to get pregnant now, but I would like to get pregnant within the next six months (Continue)
- 3 I would like to get pregnant sometime in the future, but not in the next six months (Thank and terminate. Request permission to recontact in three months regarding study eligibility.)
- 4 I do not ever wish to get pregnant (Thank and terminate)

Q24. In the past 12 months, have you received any type of birth control shot, such as Depo-Provera?

- 0 No (Continue to Q25)
- 1 Yes (Thank and terminate)

If 1 in Q21: Inform respondent that women who received a birth control shot in the last year are ineligible for the study.

Q25. Which of the following statements best describes your use of birth control in the past month? By birth control, I mean anything that you might have done to prevent pregnancy.

- 1 I did not have sexual intercourse in the past month because I did not want to become pregnant (**Eligible**, skip to paragraph before Q27)
- 2 I did not have sexual intercourse in the past month for other reasons (**Eligible**, skip to paragraph before Q27)
- 3 I didn't use any birth control when I had sexual intercourse (Continue to Q26)
- 4 I used birth control every time that I had sexual intercourse in order to avoid getting pregnant (**Eligible**, skip to paragraph before Q27)
- 5 I used birth control when I thought there was a risk of getting pregnant (**Eligible**, skip to paragraph before Q27)

Q26. When did you and your partner last use some form of birth control?

- 00 Have never used birth control
- 01-98 Specify months: _____

If Q26=00 or Q26>02 months, thank and terminate.
Otherwise eligible, continue. (**Eligible**)

Thank you for your cooperation in answering my questions. Based on your answers, you and your husband (partner) are eligible to participate in our important research project, the LIFE Study. We are currently seeking couples for this study who are thinking about trying to become pregnant within the next six months. If you and your partner choose to participate in the LIFE Study, you will be asked to keep a journal and complete a series of questionnaires as you try to get pregnant. As an incentive for participation, we will provide you with a digital fertility monitor that will help you to identify your fertile period. The monitor will be yours to keep, even after the study has been completed. You will also be given free home pregnancy test kits so that you can learn that you are pregnant as soon as possible. In addition, if you and your husband (partner) are willing to provide us with specimens such as blood and urine for the measurement of environmental pollutants, you will each be paid up to \$75.

Q27. I'd like to have our research nurse contact you so that she can explain additional details about the study and possibly schedule a time to meet with you and your husband (partner). Would it be okay if I ask her to give you a call?

- 0 No, respondent not interested (Continue to Q28)
- 1 Yes, respondent is interested in learning more (Skip to Q29)

Q28. Which of the following reasons best describes why you are not interested in learning more about this important study. Please tell me all that apply. Is it that:

- 1 You are too busy
- 2 You are not interested in participating in a research project
- 3 You don't think that your husband (partner) will be interested in participating
- 4 Some other reason, please specify: _____

If Q28=1 or Q28=2 or Q28=3 or Q28=4 then thank and terminate.

Q29. I'd like to verify your phone number. I have your number listed as (read phone number). Is that correct?

- 0 No, Specify correct number: _____
- 1 Yes

Q30. Is this the best number at which to reach you?

- 0 No, Specify best number: _____
- 1 Yes

Q31. What is the best time to reach you?

Specify day/time: _____

Appendix A – Informed Consent Passage, Males

TITLE OF PROJECT: Eligibility Interview for the Longitudinal Investigation of Fertility and the Environment (LIFE) Study

PRINCIPAL INVESTIGATOR: PI of Individual Study Site

PURPOSE OF STUDY OR RESEARCH:

The purpose of this project is to identify eligible couples who might be interested in participating in a study focusing on how lifestyle and the environment might affect a couple's ability to have a baby.

ELIGIBILITY:

You were selected to be interviewed because you are a man residing in the [redacted] area (who has purchased a fishing license).

SPONSOR:

The study is being conducted by Individual Study Site and two participating federal agencies, the National Institute of Child Health and Human Development, and the Centers for Disease Control and Prevention.

PROCEDURES:

Your participation in this project is entirely voluntary and initially will require only a 5 to 10 minute telephone interview. The telephone interview will be scheduled at a time that is convenient for you. Following the telephone interview, you may be asked to participate further.

POSSIBLE RISKS AND DISCOMFORTS:

You may find that some of our questions are personal, especially the questions related to your reproductive history and pregnancy intentions. In addition, some people are concerned that their personal information might be shared with others.

CONFIDENTIALITY:

Your responses to the interview will be kept strictly confidential. The information will be kept in a locked file. Only the personnel authorized by the Individual Study Site principal investigator will have access to this locked file. Information you provide will only be used for this project and your individual responses will not be shared with others. When the results of this project are reported, the women who participated will not be named or identified in any way. This study has been approved by the Ethics Review Board at each participating institution.

POSSIBLE BENEFITS:

If you agree to participate in this interview, there may or may not be any direct benefit to you. We hope that the information gained will help us to identify eligible couples who might be interested in participating in an important study that will help us learn more about how lifestyle and the environment might affect a couple's ability to have a baby.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

Participation is entirely voluntary. You are free to refuse to answer any question and may terminate your participation at any time during the interview process.

REQUEST FOR MORE INFORMATION:

You may ask questions about the study at any time. If, during the interview or later, you have questions about this project, you should contact the Principal Investigator, **PI of Individual Site**, at **(XXX) XXX-XXXX**.

VERBAL CONSENT:

This is to certify that I have explained to _____ the purpose of this research, the procedures required, and the risks and benefits of participation to the best of my ability.

Research Assistant

Date

Appendix B – Informed Consent Passage, Females

TITLE OF PROJECT: Eligibility Interview for the Longitudinal Investigation of Fertility and the Environment (LIFE) Study

PRINCIPAL INVESTIGATOR: PI of Individual Study Site

PURPOSE OF STUDY OR RESEARCH:

The purpose of this project is to identify eligible couples who might be interested in participating in a study focusing on how lifestyle and the environment might affect a couple's ability to have a baby.

ELIGIBILITY:

You were selected to be interviewed because you are a woman residing in the [redacted] area.

SPONSOR:

The study is being conducted by Individual Study Site and two participating federal agencies, the National Institute of Child Health and Human Development, and the Centers for Disease Control and Prevention.

PROCEDURES:

Your participation in this project is entirely voluntary and initially will require only a 5 to 10 minute telephone interview. The telephone interview will be scheduled at a time that is convenient for you. Following the telephone interview, you may be asked to participate further.

POSSIBLE RISKS AND DISCOMFORTS:

You may find that some of our questions are personal, especially the questions related to your reproductive history and pregnancy intentions. In addition, some people are concerned that their personal information might be shared with others.

CONFIDENTIALITY:

Your responses to the interview will be kept strictly confidential. The information will be kept in a locked file. Only the personnel authorized by the Individual Study Site principal investigator will have access to this locked file. Information you provide will only be used for this project and your individual responses will not be shared with others. When the results of this project are reported, the women who participated will not be named or identified in any way. This study has been approved by the Ethics Review Board at each participating institution.

POSSIBLE BENEFITS:

If you agree to participate in this interview, there may or may not be any direct benefit to you. We hope that the information gained will help us to identify eligible couples who might be interested in participating in an important study that will help us learn more about how lifestyle and the environment might affect a couple's ability to have a baby.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

Participation is entirely voluntary. You are free to refuse to answer any question and may terminate your participation at any time during the interview process.

REQUEST FOR MORE INFORMATION:

You may ask questions about the study at any time. If, during the interview or later, you have questions about this project, you should contact the Principal Investigator, **PI of Individual Site**, at **(XXX) XXX-XXXX**.

VERBAL CONSENT:

This is to certify that I have explained to _____ the purpose of this research, the procedures required, and the risks and benefits of participation to the best of my ability.

Research Assistant

Date

OMB# 0925-0543

Exp.06/30/2010

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