OMB #: 0925-0661
Expiration Date: 06/30/2015

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Title: A methodological study to assess mental disorders for National Children's Study birth

parents Principal Investigator: Thomas McLaughlin, Sc.D.

Sponsor: The National Children's Study (NCS) is a partnership between institutions in your community and four federal agencies: 1) The Eunice Kennedy Shriver National Institute of Child Health and Human Development; 2) the National Institute of Environmental Health Sciences; 3) the U.S. Environmental Protection Agency; and, 4) the Centers for Disease Control and Prevention.

Research Subject's Name:_____Date:_____

Why are you being invited to take part in a research study?
You are asked to take part because you are 18 or older, you live in Worcester County, and you are a pregnant woman or have just delivered a baby in the past four weeks, or you are an expectant or new parent.

What should you know about a research study?
Your participation is entirely voluntary.

You may decide not to take part or decide to quit the study at any time, without any changes in the quality of the health care you receive.

You will be told about any new information or changes in the study that might affect your willingness to participate.

Why are we doing this research?
The National Children's Study is a long-term study that will follow children from birth through the age of 21. It seeks to understand the link between children's physical and emotional health, their development, and their environment in which they are raised. Untreated mental disorders in parents are risk factors for children's mental disorders. A screening instrument for mental disorders can identify parents who may be at risk for a mental disorder. The purpose of this research study is to test a parental mental health telephone questionnaire called the Parental Mental Health Screener (PMHS). The goal is to see if the PMHS can accurately detect mental disorders (e.g. depression, anxiety), and assess substance use, if they are present, through asking a series of questions. If the PMHS is found to be accurate, it may be used by the National Children's Study (NCS) as part of its questionnaire packet.

Public reporting burden for this collection of information is estimated to average 10 minutes. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0661). Do not return the completed form to this address.

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How long will the research last?
We expect that you will be in this research study until you complete one ten-minute interview and possibly a second 30-minute interview. You may also be asked to provide a saliva sample and to complete a 5-minute quality assurance interview. All study activities would be completed over the course of 48 hours. From the time you agree to be in the study until all interviews are complete may be as long as one month, based on your availability to complete study activities.

How many people will be studied?
We expect about 1200 people will be in this research study. About 400 of these will be asked to complete the second interview.

What happens if I say yes, I want to be in this research?
There are three parts to this study:

1. The Parental Mental Health Screener (PMHS)
    a. An interviewer will schedule a time with you to complete both the PMHS and a second interview called the Composite International Diagnostic Index (CIDI) by phone.
    b. At the agreed upon time, the interviewer will call you and ask a series of questions from the PMHS. This interview will last approximately 10 minutes*.
    c. At the end of this interview, the interviewer will let you know if you have been randomly selected to complete the second interview (the CIDI). If you have not been chosen, you are finished with this research study. If you have been selected, the interviewer will confirm your appointment time for the second call.
2. The Composite International Diagnostic interview (CIDI)
    a. At the agreed upon time, the interviewer will call you and ask a series of questions from the CIDI. This interview will last approximately 30 minutes*.
3. Collection of a saliva sample (Optional)
    a. If you enroll in person (not by phone), you will be given directions about how to provide a small sample of saliva (about ½ of a teaspoon) by spitting into a test tube. The saliva will be used to measure the length of part of your genetic material called the telomere. The length of the telomere may be related to stress. Saliva samples will be stored temporarily in a UMass storage room until they are sent to a lab for testing. The locked storage room is accessible only to UMass National Children's Study and facilities personnel. After the samples are tested, they will be destroyed by the testing lab according to their procedures. This part of the research is optional. You can still participate in the interviews if you do not want to give a saliva sample.

During the course of the research study, you will not be asked to make any changes to your prenatal care or daily health routine.

*Some interviews may be recorded for quality assurance of the interviewer. You will be told before the interview begins if your interview is to be recorded. Further, for quality assurance, study staff will make follow- up calls to a small percentage of participants to ask questions about the interview itself. The call will last approximately 5 minutes.

What are the risks of being in this study?

1. You may feel uncomfortable when asked about emotional, behavioral, or substance use difficulties.
2. There is a risk that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything to make sure that your information is protected.

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3. Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future.
4. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you do not share information about taking part in this study, you will reduce this risk.
5. For the second interview, you may be interviewed by a licensed interviewer who, by Massachusetts State law, is a mandated reporter and would be required to report incidents of abuse or neglect of a child, a handicapped person, or an elderly person, or intention to harm yourself or another person.

Will this study help me in any way?
There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

Will being in this study cost me any money?
There will be no additional cost to you from being in this research study

What happens to information about me?

Efforts will be made to limit access to your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Your research records will be private to the extent allowed by law, and will be disclosed only with your permission or as required by U.S. or state law. In research records, you will be identified by a code number. Research information that directly identifies you (including your name, address, phone number, and email address) may be viewed by people that have an identified role in oversight of this study and they may inspect your research records. This includes the study sponsor (the National Children's Study), their partners or contractors, as well the UMass Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects). All of these individuals are asked not to reveal your identity to others.

Will I be given any money or other compensation for being in this study?
You will receive a $25 gift card by mail after you have completed the (first) 10 minute telephone interview. If you are also randomly chosen to participate in the (second) 30-minute telephone interview, you will receive an additional $25 gift card by mail as a thank you for completing this interview.

What happens if I do not want to be in this research?
If you decide not to take part in the research, it will not affect your usual care and it will not be held against you. The only alternative to participating in this study is not to participate.

What happens if I say yes, but I change my mind later?
You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that has already been used will remain part of the study database and may not be removed in order to maintain the integrity of the research. However, any identifiable information will be destroyed so that no one can tell the data belonged to you. If you decide to stop your participation, we may ask

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if you are willing to have us contact you for safety follow-up purposes.

Can I be removed from the research without my OK?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include

- The investigator decides that continuing in the study would be harmful to you.
- The study is canceled by National Children's Study or the University of Massachusetts Medical School Institutional Review Board.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the Principal Investigator, **Dr. Thomas McLaughlin at 508-856-3132.** A listing of resources for mental health services is available upon request from the Parental Mental Health Study Office at 508-856-3699.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research and complete the study interview(s)
In addition, please indicate your permission for the following:

	Yes	No
I am willing to give a saliva sample for the study to use to obtain my genetic information	☐	☐

_____ _____

Signature of subject Date

_____

Printed name of subject

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent

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