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.

The National Children's Study Worcester County is composed of a team of community members, health professionals, and other individuals trained to carry out the national study in your area. The local partners include: National Children's Study Worcester County

Research Subject's Name:_____Date:_____

Invitation to Take Part and Introduction

You are invited to volunteer for a research study. You are asked to take part because you are 18 or older and are a pregnant woman or have just delivered a baby in the past four weeks or you are the male partner ("father") of a pregnant woman. A total of 1,200 pregnant women and their male partners will participate in the study in Worcester Co.

Purpose of Research

The purpose of this research study is to test a parental mental health telephone questionnaire called the Parental Mental Health (PMH) Screen. The goal is to see if the PMH screen can accurately detect mental disorders (e.g. depression, anxiety) if they are present through asking a series of questions. If the PMH screen is found to be accurate, it will be used by the National Children's Study (NCS) as part of its questionnaire packet.

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. Approximately 20% of the adult U.S. population has a diagnosable mental disorder during a given year and that rate has steadily increased over the past several decades. Women are more likely than men to have depression or anxiety. Pregnant women are at an increased risk for these disorders. Untreated mental disorders in parents are risk factors for children's mental disorders. A screening instrument for mental disorders can identify women who may be at risk for a mental disorder. If a pregnant woman is found to be at risk for a

disorder, they can be referred for treatment.

It is hoped that the PMH Screen is able to accurately identify pregnant women who may have a mental disorder by being administered over the telephone.

Your Rights
It is important for you to know that:

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.

PROCEDURES

There are two parts to this study:

1. The Parental Mental Health Screen
    a. All pregnant women and men who agree to participate in this study will provide a phone number to the research assistant and they will schedule a time for a telephone call.
    b. At the agreed upon time, the research assistant will call the pregnant woman or man. The research assistant will ask the individual a series of questions from the PMH Screen. This call will last approximately 10 minutes.
2. The Composite International Diagnostic interview (CIDI)
    a. Half of the men and half of the women in the study will be randomly chosen to participate in a second phone call. This means that you will have a 50-50 chance of being chosen for this second phone call (like choosing heads/tails and then flipping a coin). This time questions from a mental health screening instrument called the Composite International Diagnostic interview will be asked. This phone call will last approximately 30 minutes.

Your participation in the research will last up to one month.

CONFLICT OF INTEREST DISCLOSURE
None

RISKS

This study involves no more than minimal risk. The only discomfort associated with this study is discomfort one may feel when asked about emotional, behavioral, or substance use difficulties.

There is a risk of loss of confidentiality because some study personnel will have access to your name and telephone number, although many efforts will be made to maintain your confidentiality.

If you tell us, or we observe, that a child, a handicapped person, or an elderly person is being abused or neglected, or that you intend to do harm to yourself or another person, then we are required by law to report this to the proper authorities. Such a report might result in an investigation which could cause you significant emotional discomfort.

UNKNOWN RISKS

There may be risks to participating in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed.

PREGNANCY

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

BENEFITS

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

REASONS YOU MIGHT BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT

You may be taken out of the research study if:

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

ALTERNATIVES

The only alternative to participating in this study is not to participate.

COSTS

There will be no additional cost to you from being in this research study.

COMPENSATION

Compensation for Participation

You will receive a monetary token of appreciation of $25 for completing the (first) 10 minute telephone survey for this research, once the study data are collected. If you are also randomly chosen to

participate in the (second) 30-minute telephone interview, you will receive an additional $25 monetary token of appreciation for completing the second interview.

Reimbursement
You will not be reimbursed for any out of pocket expenses such as parking or transportation fees.

CONFIDENTIALITY

Your privacy is important to us. Your research records will be secure to the extent permitted 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, hospital medical record number or social security number) may be viewed by people that have an identified role in oversight of this study and they may inspect your medical and research records. This includes the study sponsor (the National Children's Study), their partners or contractors, as well as US Food and Drug Administration (FDA), the UMass Institutional Review Board and UMass representatives. All of these individuals are required to keep all information confidential.

YOUR PARTICIPATION IN THIS PROJECT IS ENTIRELY VOLUNTARY. YOU MAY WITHDRAW FROM THE STUDY AT ANY TIME.

THE QUALITY OF CARE YOU RECEIVE AT THIS HOSPITAL WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

RESEARCH INJURY COMPENSATION

If you are injured or have any harmful effects as a direct result of your being in this research, treatment will be made available to you at UMass Memorial Medical Center (UMMMC). You will not have to pay any charges resulting from the harmful effect or injury of any procedure that would not have otherwise been done as part of your regular care.

The *NCS Worcester County site* does not routinely provide any other form of compensation for injury. It is important that you report any suspected study-related injury to the research team listed at the top of this form immediately.

QUESTIONS

Before you sign this consent form, please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, or if you have concerns or complaints, or think the research has hurt you, you may contact Dr. *Thomas McLaughlin* at *508-856-3132,* the Principal Investigator. You may take as much time as needed to think this over. If at

any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the research study, you may contact the Administrative Coordinator for the Committee for the Protection of Human Subjects in Research at UMMS. The telephone number is (508) 856-4261.

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

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

Principal Investigator: Thomas McLaughlin, Sc.D.

Subject's Name:_____

I understand the purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result. I have been told that unforeseen events may occur. I have had an opportunity to discuss the risks and benefits of this research with the investigator and all of my questions have been answered. I agree to participate as a volunteer in this research project. I understand that I may end my participation at any time. I have been given a copy of this consent form.

_____ Date:_____
Subject's signature

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, have fully explained the details of this clinical study as described in the consent form to the subject named above.

_____ Date: _____
Signature of person obtaining consent