UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-Up Study of Home Visiting Intervention

Parent Permission/Consent Form – Office Interview

Investigators: Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester;

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You and your child ("study child") are being asked to participate in this study because you took part in the Nurse Home Visitation for Mothers and Children Study.

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you and the study child will be interviewed in the New Mothers Study Office during one visit for approximately 3 hours. Some questions in your and your child's interviews will be asked face-to-face. You and your child will be able to answer other questions directly on the computer with headphones to offer more privacy. Your own interview questions will be similar to those you were asked in the past, and will be about topics like your employment, education, use of welfare, subsequent children, and relationships. Your son's or daughter's interview will focus on development and behavior, including sexual behaviors. We will ask about your and your child's experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by your child will remain confidential and you will not be advised of your child's responses unless the information is a safety risk to your child or to others.

We will obtain your and your child's height, weight, and blood pressure. Your child will be asked to provide a urine specimen which will be tested for substance use and sexually transmitted infections. S/he will call to obtain the results of the testing for infections. As minors in Tennessee may obtain treatment for positive test results without parental consent, parents will not be notified of any positive results;

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however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where your child currently resides. If an infection is found, the culture report will be sent to the care provider of the adolescent's choice. If an infection is found, your child will be offered treatment at Planned Parenthood, or at a site of his/her choice at no cost.

You and your child each will be asked to provide a sample of your saliva. We will use the saliva to test for genes that may affect moods and behaviors. The samples will be sent with a code but without your or your child's name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your confidentiality will be maintained at all times. The DNA from your saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your and your child's DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your child's school record after receiving your signed permission on a separate release form. In addition, we will ask your child's teacher to complete a checklist about his/her classroom behavior. We also plan as before, with your signed permission on separate release forms, to access data from Departments of: Children's Services, Human Services, Health-Office of Vital Records, Tenn. Care, Finance and Administration, and Labor and Employment for you and your children.

RISKS OF PARTICIPATION: As in earlier interviews, some of the questions deal with personal information and may be sensitive. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
6. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

BENEFITS OF PARTICIPATION: Your child will receive testing for sexually transmitted infections and will be offered treatment at Planned Parenthood at no cost if found to have a sexually transmitted

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infection for which treatment is recommended. Additionally, you and your child may benefit from information on your blood pressure and BMI, and information on agencies and services available in the community.

ALTERNATIVES: You and your child may choose to participate or not to participate in this study, or you may choose to withdraw at any time. Your child may choose to have STD testing and treatment and counseling related to health behaviors through his/her regular source of health care.

COSTS: There will be no cost to you to participate in this research study. We also will arrange to cover the cost of transportation to the office, if needed, and child care for other children at our office if needed while you are at the interview.

PAYMENTS: We will give you a debit card for $130 for your participation. We also will give your child a debit card for $100 for his/her participation. In addition, if you keep your interview appointment as scheduled the first time, we will give you an additional $20.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you and your child private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you and your child that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, saliva sample. We will also collect urine from your child.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; Tenn. Care; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment; Tennessee Department of Finance and Administration; and your child's schools.

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Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

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. However, if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your child is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your child's right to privacy, the results of this research may be presented at meetings or in publications; however, your and your child's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort, contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642

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If you have any questions about your rights as a research subject, or any concerns or complaints you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303) - 724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason without risking loss of present or future care you would expect to receive. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for me and my child to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT:

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____ SIGNATURE _____DATE

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your and your child's samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

My Sample My Child's Sample

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_____ _____ YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to me and the information I have provided in this study.

_____ _____ YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to me.

_____ _____ NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

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Seventeen-Year Follow-Up Study of Home Visiting Intervention

Parent Only (Child over age 18) - Consent Form – Office Interview

Investigators: Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because you took part in the Nurse Home Visitation for Mothers and Children Study. We will also invite your oldest child ("study child") who has previously taken part in this study, to participate in this study again now, and get his/her consent if he/she wishes to participate.

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed in the New Mothers Study Office during one visit for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview questions will be similar to those you were asked in the past and will be about your employment, education, use of welfare, subsequent children, and relationships. We will ask about your and your child's experiences with school and at home, as well as about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by you will remain confidential.

We will obtain your height, weight, and blood pressure. You will be asked to provide a sample of your saliva. We will use the saliva to test for genes that may affect moods and behavior. The samples will be sent with a code but without your name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your confidentiality will be maintained at all times. The DNA from your saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your DNA and health information

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for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your child's school record after receiving your signature on a separate release form. In addition, we will ask your child's teacher to complete a checklist about his/her classroom behavior. We also plan, as before, with your signed permission on separate release forms, to access data from Departments of: Children's Services, Tenn. Care, Human Services, Health-Office of Vital Records Finance and Administration, and Labor and Employment for you and your children.

RISKS OF PARTICIPATION: As in earlier interviews, some of the questions deal with personal information and may upset you. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
6. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

BENEFITS OF PARTICIPATION: Your child will receive testing for sexually transmitted infections and will be offered treatment at Planned Parenthood at no cost if found to have a sexually transmitted infection for which treatment is recommended. Additionally, you and your child may benefit from information on your blood pressure and BMI, and information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study, or you may choose to withdraw at any time.

COSTS: There will be no cost to you to participate in this research study. We will arrange to cover the cost of transportation to the office, if needed, and child care for other children in our office if needed while you are at the interview.

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PAYMENTS: We will give you a debit card for $130 for your participation. In addition, if you keep your interview appointment as scheduled the first time, we will give you an additional $20.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you and your child private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, saliva sample.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: National Institute of Health, The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; Tenn. Care; Tennessee Department of Finance and Administration; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment, a and your child's schools.

Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators

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have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

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. However, if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your child is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your child's right to privacy, the results of this research may be presented at meetings or in publications; however, your and your child's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort please contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585) 276-0005; long distance you may call toll free: (877) 449-4441 or Colorado Multiple Institutional Review Board at: (303) 724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason without risking loss of present or future care you would otherwise expect to receive. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for me to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Study subject: _____PRINT NAME

Study subject/: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____ SIGNATURE _____DATE

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your sample could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

_____ YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to me and the information I have provided in this study.

_____ YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to me.

_____ NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

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Seventeen Year Follow-Up Study of Home Visiting Intervention

YOUTH ASSENT FORM FOR SUBSEQUENT CHILDREN (CHILD # _____)

Investigators: Harriet J. Kitzman, Ph.D., FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, Ph.D., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

You are being asked to take part in a research study because your mother and your older sibling previously participated in the Nurse Home Visitation for Mothers and Children Study. Your parent, or guardian, has given permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. You don't have to be a part of this study, or you can quit any time you want, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or your health care provider.

This form will tell you what you can expect if you decide to participate in this research study. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this assent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

WHAT IS THE PURPOSE OF THE STUDY?

We are learning how mothers and their sons and daughters are doing many years after they first participated in this research study. The study was designed to help us learn how to provide better health care to mothers and their children. We're asking you to help us learn more by being part of this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

If you decide to be in this study, you will one of approximately 2,004 people in this research study.

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WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

If you agree to participate today, all together for this one visit, it will take about 3 hours. A person from our research staff will ask you to do some math and reading activities similar to those you do in school and will then ask you questions. The kinds of questions we will ask you include some questions on exercises you do, your experience at school, at home and in the community, your development and behavior, including sexual and possible delinquent behaviors, such as whether you have tried drugs or sold drugs. Some of these questions may be personal. If any of these questions make you feel uncomfortable, you do not have to answer them and you can stop the interview at any time. The answers you give us and the results of the tests will be confidential and will not be given to anyone, including your mother/guardian unless you or others are in danger.

Today, we will obtain your height, weight, and blood pressure. We also will ask you to give us a sample of your urine and your saliva. We will send the urine sample to a laboratory to be tested for substance use and sexually transmitted infections. We will ask you to call to learn the results of the testing for infections. Because minors in Tennessee may obtain treatment for positive test results without parental consent, parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where you currently reside. If you do have an infection, we will send the results to Planned Parenthood, your primary care physician or a physician of your choice. If an infection is found, you will be offered treatment at Planned Parenthood, or at a site of your choice at no cost. We will use the saliva to test for genes that may affect moods and behavior. The nurse will give you directions about how to provide the urine and the saliva samples and how to learn the results of your test for sexually transmitted infections.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS INVOLVED WITH BEING IN THIS STUDY?

Some of the questions deal with personal information and may upset you. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.

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4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
6. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS STUDY?
The benefits to you from being in this study may be that you can be tested for sexually transmitted infections and if your test is positive, you can receive treatment at no cost to you from Planned Parenthood. You may also learn about your blood pressure and BMI, and about information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study or you may choose to withdraw at any time. You may choose to have counseling related to health behaviors through your regular source of health care.

COSTS: There will be no cost to you to participate in this research study. We will arrange to cover the cost of your transportation, if needed, to the study office so that you can do the interview.

WILL YOU RECEIVE ANYTHING FOR BEING IN THE STUDY?
For your participation, we will give you a bank card totaling $100.

WHO IS SPONSORING THIS STUDY?
This research is funded by the National Institute on Drug Abuse (NIDA). This means that the research team is being paid by the sponsor for doing the study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and urine and saliva samples. We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

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To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Department of Children's Services; Tenn. Care; Department of Human Services, Department of Finance and Administration; National Institute of Health and your schools.

Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. The project staff respects your desire for privacy. If, however, concerns arise about your welfare, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns.

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Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:
To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303)- 724-1055).

VOLUNTARY PARTICIPATION:
Whether or not you participate in this study is up to you. You don't have to take part, or if you start, you can stop at any time, for any reason. If you decide to start or stop, it won't change any medical care that you are receiving from any medical care provider. If you do decide to stop, we will not tell other people about the information we have collected.

SIGNATURE/DATE:
I have read this form (or have had it read to me). If I had questions, they were answered. I agree to be in this study.

Study Subject: _____ Print name

Study Subject: _____ Signature

_____ Date

PERSON OBTAINING ASSENT:
I have read this form to the subject or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

_____ Print Name and Title

_____ Signature _____Date

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

My Sample

_____YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to me and the information I have provided in this study.

_____YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to me.

_____NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

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Seventeen-Year Follow-Up Study of Home Visiting Intervention

PARENT ONLY (Child over age 18) CONSENT FORM – BRIEF OFFICE INTERVIEW
SUBSEQUENT CHILD (Child # _____)

Investigators: Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester;

INTRODUCTION:
This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because you took part in the Nurse Home Visitation for Mothers and Children Study. We will also invite your subsequent child to participate in the study and obtain your consent if s/he wishes to participate.

PURPOSE OF STUDY:
This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:
If you decide to take part, you will be interviewed about your "subsequent child" in the New Mothers Study Office during one visit for approximately 45 minutes. Some questions in your interview will be asked face-to-face, and some questions will be answered directly on the computer. We will ask you some questions about your and your subsequent child's experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by you will remain confidential unless the information is a safety risk to you or to others.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
If you decide to be in this study, you will be one of approximately 2,004 people in this research study.

RISKS OF PARTICIPATION: As in earlier interviews, some of the questions deal with personal information and may be sensitive. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

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BENEFITS OF PARTICIPATION: You may benefit from information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study, or you may choose to withdraw at any time.

COSTS: There will be no cost to you to participate in this research study. We also will arrange to cover the cost of transportation to the office, if needed, and child care for other children at our office if needed while you are at the interview.

PAYMENTS: We will give you a debit card for $30 for your participation.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; Tenn. Care; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment; Tennessee Department of Finance and Administration; and your subsequent child's schools.

Records about you and will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are

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otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your child is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your child's right to privacy, the results of this research may be presented at meetings or in publications; however your and your child's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort, contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, or any concerns or complaints you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303) - 724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

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VOLUNTARY PARTICIPATION/TERMINATION:
Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason without risking loss of present or future care you would expect to receive. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for me to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT:
I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____ SIGNATURE _____DATE

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UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-Up Study of Home Visiting Intervention

PARENT PERMISSION/CONSENT FORM – OFFICE INTERVIEW
SUBSEQUENT CHILD (Child # _____)

Investigators: Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester;

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you will take part. You and your child are being asked to participate in this study because you took part in the Nurse Home Visitation for Mothers and Children Study.

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed about your "subsequent child" in the New Mothers Study Office during one visit for approximately 45 minutes. Some questions in your interview will be asked face-to-face, and some questions will be answered directly on the computer. We will ask you some questions about your and your subsequent child's experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by you will remain confidential unless the information is a safety risk to you or to others.

If you decide to let your child take part in this study, he/she will be interviewed in the New Mothers Study Office during one visit for approximately 3 hours. Some questions in your child's interview will be asked face-to-face. Your child will be able to answer other questions directly on the computer with headphones to offer more privacy. Your child's interview questions will be similar to those your first child ("study child") was asked in the past. Your child's interview will focus on development and behavior, including sexual behaviors. We will ask about your child's experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by your child will remain confidential and you will not be advised of his/her responses unless the information is a safety risk to him/her or to others.

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We will obtain your child's height, weight, and blood pressure. Your child will be asked to provide a urine specimen which will be tested for substance use and sexually transmitted infections. He/she will call to obtain the results of the testing for infections. As minors in Tennessee may obtain treatment for positive test results without parental consent, parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where your child currently resides. If an infection is found, the culture report will be sent to the care provider of the adolescent's choice. If an infection is found, your child will be offered treatment at Planned Parenthood, or at a site of his/her choice at no cost.

Your child will be asked to provide a sample of saliva. We will use the saliva to test for genes that may affect moods and behaviors. The samples will be sent with a code but without your child's name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. His/her confidentiality will be maintained at all times. The DNA from his/her saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your child's DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of his/her DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your child's school records after receiving your signed permission on separate release forms. In addition, we will ask your child's teachers to complete checklists about his/her classroom behavior. We also plan as before, with your signed permission on separate release forms, to access data from Departments of: Children's Services, Human Services, Health-Office of Vital Records, Tenn. Care, Finance and Administration, and Labor and Employment for you and your children.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

If you decide to let your child be in this study, he/she will be one of approximately 2,004 people in this research study.

RISKS OF PARTICIPATION: Some of the questions deal with personal information and may be sensitive. Your child's reputation may be at risk if others were to learn information he/she shared during his/her interview about his/her behaviors, and could be at risk for being questioned by authorities if others were to learn information he/she shared during his/her interview. However, every effort has been taken to insure your child's confidentiality before, during, and after the interview is conducted so as not to have interview information connected to him/her by name, or identified as his/hers in any other manner.

Under some circumstances it can be a risk for genetic information about your child to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. Your child will not have access to this information.
4. We will not release any information about your child to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.

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5. The genetic testing laboratory at NIH will not have access to your child's name or any personal details that could identify him/her.
6. Your child's data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your child's name to his/her genetic information requires additional passwords and will only be possible for a short time after his/her DNA is analyzed.

BENEFITS OF PARTICIPATION: Your child will receive testing for sexually transmitted infections and will be offered treatment at Planned Parenthood at no cost if found to have a sexually transmitted infection for which treatment is recommended. Additionally, your child may benefit from information on his/her blood pressure and BMI, and information on agencies and services available in the community.

ALTERNATIVES: Your child may choose to participate or not to participate in this study, or may choose to withdraw at any time. Your child may choose to have STD testing and treatment and counseling related to health behaviors through his/her regular source of health care.

COSTS: There will be no cost to you or your child to participate in this research study. We also will arrange to cover the cost of transportation to the office, if needed, and child care for other children at our office if needed while he/she is at the interview.

PAYMENTS: We will give you a debit card for $30 for your participation. We will give your child a debit card for $100 for his/her participation.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about d your child private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your child's name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about your t child that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, saliva sample. We will also collect urine from your child.

We will use your child's health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let your child see and copy this information after the study ends, but not until the study is completed. If your child has never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify your child with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee

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Department of Children's Services; Tenn. Care; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment; Tennessee Department of Finance and Administration; and your child's schools.

Records about your child, including laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to let your child take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during his/her participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, your child will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Permission Form/Authorization and not be part of the study. You can also tell us you want to have your child leave the study at any time without canceling the Authorization. By signing this Permission form, you give us permission to use and/or share your and your child's health information as stated above. To further protect his/her privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify your child in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your child is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your child's right to privacy, the results of this research may be presented at meetings or in publications; however your and your child's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort, contact:

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Evelyn Collins Project Office Memphis TN (901)452-6180	David Olds, PhD University of Colorado Aurora, CO 80045 (303)-724-2892	Harriet Kitzman, FAAN, PhD University of Rochester Rochester, New York 14642 (585)-275-8874

If you have any questions about your or your child's rights as a research subject, or any concerns or complaints you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303) - 724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. Your child is free not to take part or to stop at any time, for any reason without risking loss of present or future care he/she would expect to receive. If you do withdraw your child from the study, we will keep confidential the information we have already collected.

SIGNATURE/DATES:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for my child to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT:

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____ SIGNATURE _____DATE

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your child's samples could be useful, we ask you to designate as to whether or not your child's samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

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My Child's Samples

_____ YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to my child and the information he/she has provided in this study.

_____ YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to my child.

_____ NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw your child from the study before it is completed, his/her DNA will be destroyed. Results obtained prior to your child's withdrawal from the study will be maintained and his/her privacy will be protected.

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UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-Up Study of Home Visiting Intervention

CONSENT FORM FOR SUBSEQUENT CHILD (OVER AGE 18) (Child # _____)

Investigators: Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester;

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You and your mother are being asked to participate in this study because she and your older sibling previously took part in the Nurse Home Visitation for Mothers and Children Study.

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed in the New Mothers Study Office during one visit, for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview questions will focus on your development and behavior, including sexual behaviors. We will ask about your experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information you provide will remain confidential unless the information is a safety risk to you or to others.

We will obtain your height, weight, and blood pressure. You will be asked to provide a urine specimen that will be tested for substance use and sexually transmitted infections. You will be asked to call to obtain the results of the testing for infections. Because in Tennessee you may obtain treatment for positive test results without parental consent, your parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where you currently reside. If an infection is found, the culture report will be sent to the care provider of your choice. If an infection is found, you will be offered treatment at Planned Parenthood, or at a site of your choice at no cost.

You will be asked to provide a sample of your saliva. We will use the saliva to test for genes that may affect moods and behaviors. The samples will be sent with a code but without your name to the National

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Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your confidentiality will be maintained at all times. The DNA from your saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your school records after receiving your signed permission on a separate release form. In addition, we will ask your teacher to complete checklists about your classroom behavior. We also plan to access data from Departments of: Children's Services, Human Services, Health-Office of Vital Records, Tenn. Care, Finance and Administration, and Labor and Employment.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
If you decide to be in this study, you will be one of approximately 2,004 people in this research study.

RISKS OF PARTICIPATION: Some of the interview questions deal with personal information and may be sensitive. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
6. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

BENEFITS OF PARTICIPATION: You may benefit by the testing for sexually transmitted infections and will be offered treatment at no cost if found to have a sexually transmitted infection for which treatment is recommended. You may also benefit from information on your blood pressure and BMI, and information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study, or you may choose to withdraw at any time. You may choose to have STD testing, treatment, and counseling related to health behaviors through their regular source of health care.

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COSTS: There will be no cost to you to participate in this research study. We also will arrange to cover the cost of transportation to the office, if needed, to the study office so that you can do the interview.

PAYMENTS: We will give you a debit card for $100 for your participation.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and urine and saliva samples.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; Tenn. Care; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment; Tennessee Department of Finance and Administration; your child's schools; and National Institute of Alcohol Abuse and Alcoholism.

Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

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As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

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. However, if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your family is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your family's right to privacy, the results of this research may be presented at meetings or in publications; however, your and your family's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort, contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, or any concerns or complaints you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303) - 724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason without risking loss of present or future care you would otherwise expect to receive. If you do stop taking part, we will keep confidential the information we have already collected from you.

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SIGNATURE/DATES:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT:

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____ SIGNATURE _____DATE

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

_____ YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to me and the information I have provided in this study.

_____ YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to me.

_____ NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

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UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-up of Women and Children Enrolled in Trial of Prenatal and Infancy Nurse Home Visitation

Permission/Consent Form (18 year old)-(Incarcerated)

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York; Harriet J. Kitzman, Ph.D., FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because you took part in the Memphis New Mothers Study. **Taking part in this research study will not affect your consideration for probation or parole.**

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed at your current location during one visit, for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview will be similar to those you were asked in the past, and will also focus on your development and behavior. We will ask about your experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information you provide will remain confidential unless the information is a safety risk to you or to others.

We will obtain your height, weight, and blood pressure.

You will be asked to provide a sample of your saliva. The samples will be sent with a code but without your name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your confidentiality will be maintained at all times. The DNA from your saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your school record after receiving your signed permission on a separate release form. In addition, we will ask your teacher to complete a checklist about your classroom behavior. We also plan to access data from the Tennessee State Departments of: Children's Services, Tenn. Care, Human Services, Health-Office of Vital Records (or in other states as appropriate), Finance and Administration, and Labor and Employment.

RISKS OF PARTICIPATION: This study involves some minimal risk. As in earlier interviews, some of the questions deal with personal information and may be sensitive.

RISKS OF GENETIC TESTING:
Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. A permanent source for your DNA will not be created or generated.
6. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
7. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
8. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you.

COSTS: There will be no cost to you to participate in this research study.

PAYMENTS: We will give you a debit card for $100 for your participation, and in addition, if you keep your appointment as scheduled the first time, we will give you an additional $20, unless your receiving payment is in violation of penal institution (jail, prison, etc.) policy. In the event that receipt of payment is in violation of penal institution policy, you may elect to have your payment given to a family member or other designee.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and urine and saliva samples.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be checked (audited) to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after

the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado Health Science Center; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Human Services, Tennessee Department of Finance and Administration; your child's schools; and National Institute of Alcohol Abuse and Alcoholism.

Records about you, including your genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. The project staff respects your desire for privacy. If, however, concerns arise about your welfare, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:

To find out more information about the research study and your rights contact:

Evelyn Collins Project Office Memphis TN (901)-452-6180	David Olds, PhD University of Colorado Aurora, CO 80045 (303)-724-2892	Harriet Kitzman, FAAN, PhD University of Rochester Rochester, New York 14642 (585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303)-724-1055.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future references

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____ PRINT NAME AND TITLE

_____SIGNATURE _____DATE

If samples are to be stored for future use:

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

_____YES, I give permission to use my DNA sample in future research studies under the following conditions:

_____The DNA sample may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine.

_____ The DNA sample may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

_____MAYBE. I wish to be re-contacted if further studies with my DNA sample are considered. After the study has been explained, I will then decide if I want my sample to be included.

_____NO. Under no circumstances shall my DNA sample be used for any future studies. My DNA sample should be destroyed once the present study is complete.

If you allow future research on your DNA sample and the research provides information important for your health, we will try to contact you. If you wish to be contacted, please keep the principal investigator for this study updated about changes in your address or phone number.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen Year Follow-Up Study of Home Visiting Intervention

Youth Assent Form

Investigators: Harriet J. Kitzman, Ph.D., FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, Ph.D., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

You are being asked to take part in a research study because you and your mother previously participated in the Nurse Home Visitation for Mothers and Children Study. Your parent, or guardian, has given permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. You don't have to be a part of this study, or you can quit any time you want, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or your health care provider.

This form will tell you what you can expect if you decide to participate in this research study. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this assent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

WHAT IS THE PURPOSE OF THE STUDY?

We are learning how mothers and their sons and daughters are doing 17 years after they first participated in this research study. The study was designed to help us learn how to provide better health care to mothers and their children. We're asking you to help us learn more by being part of this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

If you decide to be in this study, you will one of approximately 2,004 people in this research study.

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WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

During the last interview you completed tests; we obtained your height and weight; we asked you questions about your beliefs and behaviors; and we contacted your school to obtain information from your teacher and your records.

If you agree to participate today, all together for this one visit, it will take about 3 hours. The questions and tasks will be very similar to the last interview. A person from our research staff will ask you to do some math and reading activities similar to those you do in school and will then ask you questions. The kinds of questions we will ask you include some questions on exercises you do, your experience at school, at home and in the community, your development and behavior, including sexual and possible delinquent behaviors, such as whether you have tried drugs or sold drugs. Some of these questions may be personal. If any of these questions make you feel uncomfortable, you do not have to answer them and you can stop the interview at any time. The answers you give us and the results of the tests will be confidential and will not be given to anyone, including your mother/guardian unless you or others are in danger.

Today, we will obtain your height, weight, and blood pressure. We also will ask you to give us a sample of your urine and your saliva. We will send the urine sample to a laboratory to be tested for substance use and sexually transmitted infections. We will ask you to call to learn the results of the testing for infections. Because minors in Tennessee may obtain treatment for positive test results without parental consent, parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where you currently reside. If you do have an infection, we will send the results to Planned Parenthood, your primary care physician or a physician of your choice. If an infection is found, you will be offered treatment at Planned Parenthood, or at a site of your choice at no cost. We will use the saliva to test for genes that may affect moods and behavior. The nurse will give you directions about how to provide the urine and the saliva samples and how to learn the results of your test for sexually transmitted infections.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS INVOLVED WITH BEING IN THIS STUDY?

Just like in earlier interviews, some of the questions deal with personal information and may upset you. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.

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2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
6. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS STUDY?

The benefits to you from being in this study may be that you can be tested for sexually transmitted infections and if your test is positive, you can receive treatment at no cost to you from Planned Parenthood. You may also learn about your blood pressure and BMI, and about information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study or you may choose to withdraw at any time. You may choose to have counseling related to health behaviors through your regular source of health care.

COSTS: There will be no cost to you to participate in this research study. We will arrange to cover the cost of your transportation, if needed, to the study office so that you can do the interview.

WILL YOU RECEIVE ANYTHING FOR BEING IN THE STUDY?

For your participation, we will give you a bank card totaling $100. In addition, if you keep your interview appointment as scheduled the first time, we will give you an additional $20.

WHO IS SPONSORING THIS STUDY?

This research is funded by the National Institute on Drug Abuse (NIDA). This means that the research team is being paid by the sponsor for doing the study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and urine and saliva samples.

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We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Department of Children's Services; Tenn. Care; Department of Human Services, Department of Finance and Administration; National Institute of Health and your schools.

Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. The project staff respects your desire for privacy. If, however, concerns arise about your welfare, according to our responsibility under

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Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:
To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303)- 724-1055).

VOLUNTARY PARTICIPATION:
Whether or not you participate in this study is up to you. You don't have to take part, or if you start, you can stop at any time, for any reason. If you decide to start or stop, it won't change any medical care that you are receiving from any medical care provider. If you do decide to stop, we will not tell other people about the information we have collected.

SIGNATURE/DATE:
I have read this form (or have had it read to me). If I had questions, they were answered. I agree to be in this study.

Study Subject: _____ Print name

Study Subject: _____ Signature

_____ Date

PERSON OBTAINING ASSENT:
I have read this form to the subject or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

_____ Print Name and Title

601 Elmwood Avenue · Rochester, NY 14642
www.urmc.rochester.edu

_____ Signature _____Date

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

My Sample

_____YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to me and the information I have provided in this study.

_____YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to me.

_____NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

601 Elmwood Avenue · Rochester, NY 14642
www.urmc.rochester.edu

Seventeen-Year Follow-Up Study of Home Visiting Intervention

CONSENT FORM FOR SUBSEQUENT CHILD (INCARCERATED - OVER AGE 18) (Child # _____)

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, NY; Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You and your mother are being asked to participate in this study because she and your older sibling previously took part in the Nurse Home Visitation for Mothers and Children Study. **Taking part in this research study will not affect your consideration for probation or parole.**

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed at your current location during one visit, for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview questions will focus on your development and behavior, including sexual behaviors. We will ask about your experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information you provide will remain confidential unless the information is a safety risk to you or to others.

We will obtain your height, weight, and blood pressure.

We will review and copy your school records after receiving your signed permission on a separate release form. In addition, we will ask your teacher to complete checklists about your classroom behavior. We also plan as before, with your signed permission on separate release forms, to access data from Departments of: Children's Services, Human Services, Health-Office of Vital Records, Tenn. Care, Finance and Administration, and Labor and Employment.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
If you decide to be in this study, you will be one of approximately 2,004 people in this research study.

RISKS OF PARTICIPATION: Some of the interview questions deal with personal information and may be sensitive. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you.

ALTERNATIVES: You may choose to participate or not to participate in this study, or you may choose to withdraw at any time.

COSTS: There will be no cost to you to participate in this research study.

PAYMENTS: We will give you a debit card for $100 for your participation unless your receiving payment is in violation of penal institution (jail, prison, etc.) policy. In the event that receipt of payment is in violation of penal institution policy, you may elect to have your payment given to a family member or other designee.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the

following measures to collect information: interviews, height, weight, blood pressure, and saliva sample.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; Tenn. Care; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment; Tennessee Department of Finance and Administration; and your school, and National Institute of Alcohol Abuse and Alcoholism.

Records about you, including your genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code, or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about

your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your family is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to the proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your family's right to privacy, the results of this research may be presented at meetings or in publications; however, your and your family's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort, contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, or any concerns or complaints you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303) - 724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason without risking loss of present or future care you would expect to receive. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT:

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

Interviewer: _____ SIGNATURE

_____DATE

UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-up of Women and Children Enrolled in Trial of Prenatal and Infancy Nurse Home Visitation

Consent Form (18 year old)-(Incarcerated)

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York; Harriet J. Kitzman, Ph.D., FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:
This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because you took part in the Memphis New Mothers Study. **Taking part in this research study will not affect your consideration for probation or parole.**

PURPOSE OF STUDY:
This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:
If you decide to take part, you will be interviewed at your current location during one visit, for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview will be similar to those you were asked in the past, and will also focus on your development and behavior. We will ask about your experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information you provide will remain confidential unless the information is a safety risk to you or to others.

We will obtain your height, weight, and blood pressure.

We will review and copy your school record after receiving your signed permission on a separate release form. In addition, we will ask your teacher to complete a checklist about your classroom behavior. We also plan to access data from the Tennessee State Departments of: Children's Services, Tenn. Care, Human Services, Health-Office of Vital Records (or in other states as appropriate), Finance and Administration, and Labor and Employment.

RISKS OF PARTICIPATION: This study involves some minimal risk. As in earlier interviews, some of the questions deal with personal information and may be sensitive.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you.

COSTS: There will be no cost to you to participate in this research study.

PAYMENTS: We will give you a debit card for $100 for your participation. In addition, if you keep your appointment as scheduled the first time, we will give you an additional $20.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be checked (audited) to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Human Services, Tennessee Department of Finance and Administration; and your schools.

Records about you, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. The project staff respects your desire for privacy. If, however, concerns arise about your welfare, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:

To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303)-724-1055.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future references.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____
PRINT NAME AND TITLE

_____SIGNATURE _____DATE

601 Elmwood Avenue · Rochester, NY 14642
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UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-up of Women and Children Enrolled in Trial of Prenatal and Infancy Nurse Home Visitation

Parent Permission/Consent Form – (Incarcerated)

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester; Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You and your child ("study child") are being asked to participate in this study because you took part in the Memphis New Mothers Study. **Taking part in this research study will not affect your consideration for probation or parole.**

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed at your current location during one visit for approximately 3 hours, and the study child will be interviewed in the New Mother's Study Office. Some questions in your and your child's interviews will be asked face-to-face. You and your child will be able to answer other questions directly on the computer with headphones to offer more privacy. Your own interview questions will be similar to those you were asked in the past, and will be about topics like your employment, education, use of welfare, children, and relationships. Your son's or daughter's interview will focus on development and behavior. We will ask about your and your child's experiences with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by your child will remain confidential and you will not be advised of your child's responses unless the information is a safety risk to your child or to others. We will obtain your and your child's height, weight, and blood pressure. Your child will be asked to provide a urine specimen that will be tested for substance use and sexually transmitted infections. S/he will call to obtain the results of the testing for infections. As minors in Tennessee may obtain treatment for positive test results without parental consent, parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where your child currently resides. If an infection is found, your child will be offered treatment at Planned Parenthood at no cost.

Your child will be asked to provide a sample of saliva. The sample will be sent with a code but without your child's name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your child's confidentiality will be maintained at all times. The DNA from your child's saliva will be used up in the study described in this consent. Any remaining DNA will be

destroyed at the end of the study unless you give us permission to use your child's DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your child's DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your child's school record. In addition, we will ask your child's teacher to complete a checklist about his/her classroom behavior. We also plan, as before, with your signed permission on separate release forms, to access data from the Tennessee Departments of: Children's Services, Human Services, Health-Office of Vital Records (or other states as appropriate), Finance and Administration, and Labor and Employment for you and your children.

RISKS OF PARTICIPATION: This study involves some minimal risk. As in earlier interviews, some of the questions deal with personal information and may be sensitive.

RISKS OF GENETIC TESTING:
Under some circumstances it can be a risk for genetic information about your child to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about your child to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your child's name or any personal details that could identify your child.
6. Your child's data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your child's name to his/her genetic information requires additional passwords and will only be possible for a short time after your child's DNA is analyzed.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you and your child. Your child will receive testing for sexually transmitted infections and will be offered treatment at no cost if found to have a sexually transmitted infection for which treatment is recommended.

ALTERNATIVES: Your child may choose to have STD testing and treatment and counseling related to health behaviors through his/her regular source of health care.

COSTS: There will be no cost to you to participate in this research study.

PAYMENTS: We will give you a debit card for $130 for your participation. We also will give your child a debit card for $100 for his/her participation. In addition, if you keep your appointment as scheduled the first time, we will give you an additional $20.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:

While we will make every effort to keep information we learn about you and your child private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you and your child that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and saliva sample. We will also collect urine from your child.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Tennessee Department of Labor and Employment; The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Human Services, Tennessee Department of Finance and Administration; Tennessee (or other states as appropriate) State Department of Health-vital Records; and your child's schools.

Records about you and your child, including any laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative,

legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your and your child's identity will not be disclosed in those presentations. The project staff respects your family's desire for privacy. If, however, concerns arise about the welfare of your child or family, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:

To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585 276-0005, Long distance you may call toll free: (877) 449-441 or Colorado Multiple Institutional Review Board at: (303) 724-1055.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for me and my child to participate in this study. I have received (or will receive) a signed copy of this form for my records and future references

Study subject: _____PRINT NAME

Study subject/legal representative: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____ PRINT NAME AND TITLE

_____SIGNATURE _____DATE

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your child's samples could be useful, we ask you to designate as to whether or not your child's samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

My Child's Sample

_____ YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to my child and the information I have provided in this study.

_____ YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to my child.

_____ NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your child's DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your child's privacy will be protected.

UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-up of Women and Children Enrolled in Trial of Prenatal and Infancy Nurse Home Visitation
Other Custody Consent – Office Interview

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester; Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:
This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because the child for whom you have custody took part in the Memphis New Mothers Study. We will also invite your child ("study child") who has previously taken part in this study, to participate in this study again now, and get his/her consent if he/she wishes to participate.

PURPOSE OF STUDY:
This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:
If you decide to take part, you will be interviewed in the New Mothers Study Office during one visit for approximately 3 hours. The interview questions will be similar to those you were asked in the past if you previously took part in the study. Questions will be about your employment, education, use of welfare, subsequent children, and relationships. We will obtain your height, weight, and blood pressure. We will ask about your child's experiences with school and at home, as well as about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by you will remain confidential.

We will review and copy your child's school record. In addition, we will ask your child's teacher to complete a checklist about his/her classroom behavior. We also plan to access data from the Tennessee Departments of: Children's Services, Human Services, Health-Office of Vital Records (Tennessee and/or other states), Finance and Administration, and Labor and Employment for you and your children.

RISKS OF PARTICIPATION: This study involves some minimal risk. As in earlier interviews, some of the questions deal with personal information and may be sensitive.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you and your child. Your child will receive testing for sexually transmitted infections and will be offered treatment at Planned Parenthood at no cost if found to have a sexually transmitted infection for which treatment is recommended. Additionally, you and your child may benefit from information on your blood pressure and BMI, and information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study, or you may choose to withdraw at any time.

COSTS: There will be no cost to you to participate in this research study.

PAYMENTS: We will give you a debit card for $130 for your participation. In addition, if you keep your interview appointment as scheduled the first time, we will give you an additional $20.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure. We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Finance and Administration; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment, a and your child's schools.

Records about you will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators

have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:

To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585 276-0005, Long distance you may call toll free: (877) 449-441 or Colorado Multiple Institutional Review Board at: (303) 724-1055.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for me to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study subject: _____PRINT NAME

Study subject/legal representative: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____SIGNATURE _____DATE

601 Elmwood Avenue · Rochester, NY 14642
www.urmc.rochester.edu

UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-up of Women and Children Enrolled in Trial of Prenatal and Infancy Nurse Home Visitation

Parent Permission / Consent Form – (Incarcerated)

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester; Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You and your child ("study child") are being asked to participate in this study because you took part in the Memphis New Mothers Study. **Taking part in this research study will not affect your consideration for probation or parole.**

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed at your current location during one visit for approximately 3 hours, and the study child will be interviewed in the New Mother's Study Office. Some questions in your and your child's interviews will be asked face-to-face. You and your child will be able to answer other questions directly on the computer with headphones to offer more privacy. Your own interview questions will be similar to those you were asked in the past, and will be about topics like your employment, education, use of welfare, children, and relationships. Your son's or daughter's interview will focus on development and behavior. We will ask about your and your child's experiences with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information provided by your child will remain confidential and you will not be advised of your child's responses unless the information is a safety risk to your child or to others. We will obtain your and your child's height, weight, and blood pressure. Your child will be asked to provide a urine specimen that will be tested for substance use and sexually transmitted infections. S/he will call to obtain the results of the testing for infections. As minors in Tennessee may obtain treatment for positive test results without parental consent, parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where your child currently resides. If an infection is found, your child will be offered treatment at Planned Parenthood at no cost.

You and your child each will be asked to provide a sample of your saliva. The samples will be sent with a code but without your or your child's name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your confidentiality will be maintained at all times. The DNA from your saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your and your child's DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your child's school record. In addition, we will ask your child's teacher to complete a checklist about his/her classroom behavior. We also plan, as before, with your signed permission on separate release forms, to access data from the Tennessee Departments of: Children's Services, Human Services, Health-Office of Vital Records (or other states as appropriate), Finance and Administration, and Labor and Employment for you and your children.

RISKS OF PARTICIPATION: This study involves some minimal risk. As in earlier interviews, some of the questions deal with personal information and may be sensitive.

RISKS OF GENETIC TESTING:
Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. A permanent source for your DNA will not be created or generated.
6. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
7. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
8. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you and your child. Your child will receive testing for sexually transmitted infections and will be offered treatment at no cost if found to have a sexually transmitted infection for which treatment is recommended.

ALTERNATIVES: Your child may choose to have STD testing and treatment and counseling related to health behaviors through his/her regular source of health care.

COSTS: There will be no cost to you to participate in this research study.

PAYMENTS: We will give you a debit card for $130 for your participation, and in addition, if you keep your appointment as scheduled the first time, we will give you an additional $20, unless your receiving payment is in violation of penal institution (jail, prison, etc.) policy. In the event that receipt of payment is in violation of penal institution policy, you may elect to have your payment given to a family member or other designee. We also will give your child a debit card for $100 for his/her participation.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:

While we will make every effort to keep information we learn about you and your child private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you and your child that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and saliva sample. We will also collect urine from your child.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Tennessee Department of Labor and Employment; The Department of Health and Human Services; the University of Rochester; University of Colorado Health Science Center; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Human Services, Tennessee Department of Finance and Administration; Tennessee (or other states as appropriate) State Department of Health-vital Records; your child's school; and National Institute of Alcohol Abuse and Alcoholism.

Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative,

legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your and your child's identity will not be disclosed in those presentations. The project staff respects your family's desire for privacy. If, however, concerns arise about the welfare of your child or family, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:

To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585 276-0005, Long distance you may call toll free: (877) 449-441 or Colorado Multiple Institutional Review Board at: (303) 724-1055.

VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for me and my child to participate in this study. I have received (or will receive) a signed copy of this form for my records and future references

Study subject: _____PRINT NAME

Study subject/legal representative: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____ SIGNATURE _____DATE

If samples are to be stored for future use:

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

_____YES, I give permission to use my DNA sample in future research studies under the following conditions:

_____The DNA sample may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine.

_____ The DNA sample may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

_____MAYBE. I wish to be re-contacted if further studies with my DNA sample are considered. After the study has been explained, I will then decide if I want my sample to be included.

_____NO. Under no circumstances shall my DNA sample be used for any future studies. My DNA sample should be destroyed once the present study is complete.

If you allow future research on your DNA sample and the research provides information important for your health, we will try to contact you. If you wish to be contacted, please keep the principal investigator for this study updated about changes in your address or phone number.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen Year Follow-Up Study of Home Visiting Intervention

Consent Form (18 year old)

Investigators: Harriet J. Kitzman, Ph.D., FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, Ph.D., Professor of Pediatrics, University of Colorado Denver, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You and your mother are being asked to participate in this study because you previously took part in the Nurse Home Visitation for Mothers and Children study.

PURPOSE OF STUDY:

This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:

If you decide to take part, you will be interviewed in the New Mothers Study Office during one visit, for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview questions will be similar to those you were asked in the past, and will also focus on your development and behavior, including sexual behaviors. We will ask about your experiences with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information you provide will remain confidential unless the information is a safety risk to you or to others.

We will obtain your height, weight, and blood pressure. You will be asked to provide a urine specimen that will be tested for substance use and sexually transmitted infections. You will be asked to call to obtain the results of the testing for infections. Because in Tennessee you may obtain treatment for positive test results without parental consent, your parents will not be notified of any positive results; however by state law, any positive report of sexually transmitted infections must and will be reported to the Health Department in the county and state where you currently reside. If an infection is found, the culture report will be sent to the care provider of your choice. If an infection is found, you will be offered treatment at Planned Parenthood, or at a site of your choice at no cost.

601 Elmwood Avenue · Rochester, NY 14642
www.urmc.rochester.edu

You will be asked to provide a sample of your saliva. We will use the saliva to test for genes that may affect moods and behavior. The samples will be sent with a code but without your name to the National Institute of Health, where DNA will be taken from the cells, and it will be stored in a secure freezer. Your confidentiality will be maintained at all times. The DNA from your saliva will be used up in the study described in this consent. Any remaining DNA will be destroyed at the end of the study unless you give us permission to use your DNA and health information for other studies. The DNA also can be destroyed at your request. You can let us know if you agree to the use of your DNA for future research by checking the appropriate space at the end of this form.

We will review and copy your school record after receiving your signed permission on a separate release form. In addition, we will ask your teacher to complete a checklist about your classroom behavior. We also plan to access data from Departments of: Children's Services, Tenn. Care, Human Services, Health-Office of Vital Records, Finance and Administration, and Labor and Employment.

RISKS OF PARTICIPATION: As in earlier interviews, some of the questions deal with personal information and may upset you. Your reputation may be at risk if others were to learn information you shared during your interview about your behaviors, and you could be at risk for being questioned by authorities if others were to learn information you shared during your interview about your behaviors. However, every effort has been taken to insure your confidentiality before, during, and after the interview is conducted so as not to have interview information connected to you by name, or identified as yours in any other manner.

Under some circumstances it can be a risk for genetic information about you to be made known. The investigators in this study have taken several steps to ensure that genetic information will not be used for purposes other than research. These include the following safeguards:

1. The analyses are being performed only as research tests and not as tests for any other purpose.
2. Analyses will be restricted to the purpose of this study, that is, to examine genes that may influence mood and behavior.
3. You will not have access to this information.
4. We will not release any information about you to any family member, physician, insurance company or employer unless you sign a document allowing release of the information.
5. The genetic testing laboratory at NIH will not have access to your name or any personal details that could identify you.
6. Your data will be stored on secured, password-protected computer systems isolated from the internet. Printed data will be stored in locked cabinets in restricted areas.
7. The ability to link your name to your genetic information requires additional passwords and will only be possible for a short time after your DNA is analyzed.

BENEFITS OF PARTICIPATION: You may benefit by the testing for sexually transmitted infections and will be offered treatment at no cost if found to have a sexually transmitted infection for which treatment is recommended. You may also benefit from information on your blood pressure and BMI, and information on agencies and services available in the community.

ALTERNATIVES: You may choose to participate or not to participate in this study or you may choose to withdraw at any time. You may choose to have STD testing, treatment, and counseling related to health behaviors through your regular source of health care.

COSTS: There will be no cost to you to participate in this research study. We will arrange to cover the cost of your transportation, if needed, to the study office so that you can do the interview.

PAYMENTS: We will give you a debit card for $100 for your participation. In addition, if you keep your appointment as scheduled the first time, we will give you an additional $20.

SPONSOR STATEMENT: The University of Rochester is receiving payment from the National Institute on Drug Abuse for conducting this research study.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure, and urine and saliva samples.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: National Institute of Health, The Department of Health and Human Services; the University of Rochester; University of Colorado Health Science Center; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Human Services, Tennessee Department of Finance and Administration; your child's schools; and National Institute of Alcohol Abuse and Alcoholism.

Records about you, including your laboratory and genetic tests, will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

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. However, if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

Also, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project if they believe you or your family is at risk of abuse, at risk to hurt self or others, or has a verified communicable disease. We will discuss these concerns with you and if deemed necessary report to proper authorities in order to make sure that any needed support could be made available.

Finally, while the researchers respect your and your family's right to privacy, the results of this research may be presented at meetings or in publications; however, your and your family's identity will not be disclosed in these presentations.

CONTACT PERSONS:

To find out more information about the research study or if you feel that your participation has resulted in any emotional or physical discomfort please contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585)-275-8874

If you have any questions about your rights as a research subject, or any concerns or complaints you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877)-449-4441 or Colorado Multiple Institutional Review Board at: (303)-724-1055. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

VOLUNTARY PARTICIPATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason, without risking loss of present or future care you would otherwise expect to receive. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future references

Study Subject: _____PRINT NAME

Study Subject:_____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT:

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____PRINT NAME AND TITLE

_____SIGNATURE_____ DATE

STORING YOUR SAMPLE FOR FUTURE USE:

If a future research project arises where your sample could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line indicating your wishes.

_____ YES, I give permission to use this DNA sample for other research EVEN IF the sample can be traced through codes back to me and the information I have provided in this study.

_____ YES, I give permission to use this DNA sample for other research ONLY IF the sample can no longer be linked to me.

_____ NO. Under no circumstances shall this DNA sample be used for any future studies. This DNA sample should be destroyed once the present study is complete.

If you withdraw from the study before it is completed, your DNA will be destroyed. Results obtained prior to your withdrawal from the study will be maintained and your privacy will be protected.

UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-year Follow-up Study of Home Visiting Intervention
Daughter Interview
Assent Form

Investigators: Harriet J. Kitzman, PhD, FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York. David L. Olds, PhD, Professor of Pediatrics, University of Colorado, Denver, Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:
This assent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because you took part in the Memphis New Mothers Study.

WHAT IS THE PURPOSE OF THIS STUDY?
We are learning how daughters who have participated in the study and who are now mothers themselves, think about their roles as parents. This will help us learn more about how to help young mothers today. We're asking you to help again by participating in a new interview.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
We will interview about 40 daughters who are now mothers for this part of the study.

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS STUDY?
If you decide to take part, your interview will last about 2 hours. This interview is different from the last one you participated in. This time we will ask you about your thoughts about being a parent, and about your child's development and behavior, and how you see your role in that. If any of these questions make you feel uncomfortable, you do not have to answer them and you can stop the interview at any time. The interview will be audio taped. The answers you give us will be kept confidential and will not be shared with anyone except for persons who are part of the research team, unless you or your child is in danger.

We will not require any vital signs (heart rate or blood pressure) or height, weight, or waist measurements, or any DNA or other samples for this interview.

WHAT ARE THE POSSIBLE RISKS OF BEING INVOLVED WITH THIS STUDY?
There is a slight risk that some of the questions in the interview may make you uncomfortable. If you are uncomfortable, or for any reason, you do not have to answer any question you do not want to, and you can stop the interview at any time.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS STUDY?
The interview may be interesting and helpful for you.

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WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?
You may choose to participate or not to participate in this study or you may choose to withdraw at any time.

WHAT ARE THE COSTS TO BEING IN THIS STUDY?
There will be no costs for you to participate in this research study. We will arrange to cover the cost of your transportation, if needed, to the study office so that you can do the interview.

WILL YOU RECEIVE ANYTHING FOR BEING IN THE STUDY?
For your participation, we will give you a payment of $40.

WHO IS SPONSORING THIS STUDY?
This research is funded by the National Institute on Drug Abuse (NIDA).This means that the research team is being paid by the sponsor for doing the study.

CONFIDENTIALITY OF RECORDS AND HIPPA AUTHORIZATION:
While we will make every effort to keep information we learn about you and your children private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) require us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. For this study, the health information we will use are your answers to the interview questions.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; Tenn. Care; Tennessee and other state Departments of Health-Vital Records; Department of Labor and Employment; the Tennessee Department of Finance and Administration, National Institute of Health and your schools.

Audiotapes and the typed transcriptions of the audio taped conversations will be stored in a locked file cabinet in the principal's investigators office. The answers you give and other records about you will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are

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otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this Consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. The project staff respects your family's desire for privacy. If, however, concerns arise about the welfare of your children or family, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONTACT PERSONS:

To find out more information about the research study and your rights contact:

Evelyn Collins	David Olds, PhD	Harriet Kitzman, FAAN, PhD
Project Office	University of Colorado	University of Rochester
Memphis, TN	Aurora, CO 80045	Rochester, New York 14642
(901)-452-6180	(303)-724-2892	(585) 275-8874

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315. Telephone: (585)-276-0005; long distance you may call toll free: (877) 449-4441 or Colorado Multiple Institutional Review board at: (303)-724-1055.

VOLUNTARY PARTICIPATION:

Whether or not you participate in this study is up to you. You don't have to take part, or if you start, you can stop at any time, for any reason. If you decide to start or stop, it won't change any medical care that you are receiving from any medical care provider. If you decide to stop, we will not tell other people about the information we have collected.

SIGNATURE/DATE:

I have read this assent form (or have had it read to me). If I had questions, they were answered. I agree to be in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject: _____ Print name

Study Subject: _____ Signature

_____ Date

PERSON OBTAINING ASSENT:

I have read this assent form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

_____ Print Name and Title

_____ Signature

_____ Date

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UNIVERSITY of ROCHESTER MEDICAL CENTER

Seventeen-Year Follow-up of Women and Children Enrolled in Trial of Prenatal and Infancy Nurse Home Visitation

Subsequent Child Consent Form (18 year old)-(Incarcerated)

Investigators: David L. Olds, PhD., Professor of Pediatrics, University of Colorado Denver, Denver Colorado, and Adjunct Professor, School of Nursing, University of Rochester, Rochester, New York; Harriet J. Kitzman, Ph.D., FAAN, Professor, School of Nursing, University of Rochester, Rochester, New York.

INTRODUCTION:
This consent form describes a research study and what you may expect if you decide to participate. Please read this form carefully and ask the person who presents it any further questions you may have before you decide whether or not you want to take part. You are being asked to participate in this study because you took part in the Memphis New Mothers Study. **Taking part in this research study will not affect your consideration for probation or parole.**

PURPOSE OF STUDY:
This study was designed to help us learn how to provide better health care to mothers and children.

DESCRIPTION OF STUDY PROCEDURES:
If you decide to take part, you will be interviewed at your current location during one visit, for approximately 3 hours. Some questions in your interview will be asked face-to-face. You will be able to answer other questions directly on the computer with headphones to offer more privacy. Your interview will be similar to those you were asked in the past, and will also focus on your development and behavior. We will ask about your experience with school and at home, and will ask about possible delinquent or illegal behaviors including possible drug and alcohol use. Information you provide will remain confidential unless the information is a safety risk to you or to others.

We will obtain your height, weight, and blood pressure.

We will review and copy your school record after receiving your signed permission on a separate release form. In addition, we will ask your teacher to complete a checklist about your classroom behavior. We also plan to access data from the Tennessee State Departments of: Children's Services, Tenn. Care, Human Services, Health-Office of Vital Records (or in other states as appropriate), Finance and Administration, and Labor and Employment.

RISKS OF PARTICIPATION: This study involves some minimal risk. As in earlier interviews, some of the questions deal with personal information and may be sensitive.

BENEFITS OF PARTICIPATION: You may find the interview helpful to you.

COSTS: There will be no cost to you to participate in this research study.

P AYMENTS: We will give you a debit card for $100 for your participation. In addition, if you keep your appointment as scheduled the first time, we will give you an additional $20.

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CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION:

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use the following measures to collect information: interviews, height, weight, blood pressure.

We will use your health information to conduct the study. Health information is used to report results of research to sponsors and federal regulators. It may be checked (audited) to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; University of Colorado; Emory University; Tennessee Department of Children's Services; TennCare; Tennessee Department of Human Services, Tennessee Department of Finance and Administration; and your schools.

Records about you will be kept in a coded fashion by researchers. Only authorized people will have access to the records. The file room where data are kept is locked except during business hours. No forms will include your name, Social Security number, zip code or country.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above. To further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure may be necessary, however, upon requests of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. The project staff respects your desire for privacy. If, however, concerns arise about your welfare, according to our responsibility under Tennessee state law, we would be required to discuss these concerns with you in order to make sure that any needed support could be made available. In particular, as professionals working with children, we are required by law to report suspected child maltreatment. Should such concerns arise, we would make every effort to talk with you about these concerns.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

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VOLUNTARY PARTICIPATION/TERMINATION:

Participation in this study is voluntary. You are free not to take part or to stop at any time, for any reason. If you do stop taking part, we will keep confidential the information we have already collected from you.

SIGNATURE/DATES

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future references.

Study Subject: _____PRINT NAME

Study Subject: _____SIGNATURE

_____DATE

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have provided a signed copy of this consent form to the subject.

Interviewer: _____
PRINT NAME AND TITLE

_____SIGNATURE _____DATE

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