



CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Prospective Study of Infant Development
IRB # Pro00020974

(ADULT CONSENT)

You are being asked to take part in this study because you recently had a baby. Research studies include only those people who choose to take part. Please read this consent form carefully and take your time making your decision. As the staff member goes through this consent form with you, please ask her or him to explain any words or information that you do not clearly understand. The nature of the study, any risks or discomforts, and other important information about the study are listed below.

The study will be conducted by Dr. Kenneth Dodge and researchers with the Durham Family Initiative. The Duke Endowment is paying Duke University for this study to be completed.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to learn more about the strengths and needs of families with young children. We also want to find out how family characteristics and the services that families receive predict child health and development, parent well-being, and parenting behaviors. With this knowledge, we can develop better ways to match families with services that will benefit them.

Before you decide whether you would like to be a part of the research, you need to know more about it. We will answer any questions you have about the research.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 550 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in the research study and sign this consent form, we are asking:

1. That you participate in one interview in your home which will take approximately 1 ½ to 2 hours.
2. That you let us look at and analyze information about you and your child. Specifically:
 - a. Your child's pediatric records at your pediatric or family practice office.
 - b. Records from professional services that you may have received, including the Duke/Durham Health Department's Durham Connects universal home visiting program to see if you and your child received any services from this program.



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- c. Records from the hospital and emergency departments of Duke University Hospital and Durham Regional Hospital to review any injuries or illnesses for your child. We will look at these records until your child turns 5 years old. All data will be kept confidential.
- d. Records from the Durham Department of Social Services to see if there has been a report to the Child Protection unit about child maltreatment. We will look at these records until your child turns 5 years old. All data will be kept confidential.
- e. Birth records from the State of North Carolina.

HOW LONG WILL I BE IN THE STUDY?

You will be asked to complete one face-to-face interview when your child is approximately 6 months old. You will have no direct involvement with the study after you complete the initial interview. If we obtain funding, we may return to you in a year for another interview, and you are free to participate or to decline. You can choose to stop your involvement at any time.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks to you of being in this research. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop participation at any time. You are always free to ask questions of any Durham Family Initiative staff member.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your participation in this study will give you an opportunity to reflect on your family's circumstances and experiences and on your child's health and development. Your participation also will help us to understand the family characteristics and family services that affect child health and development, parent well-being, and parenting behaviors. With your help, we can begin to identify the strengths and needs of families with young children, and how to develop programs that deliver effective, personalized care to meet those needs.



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WILL MY INFORMATION BE KEPT PRIVATE?

All information that we obtain for this study is for research purposes only. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, neither you nor your child will be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in the office of the study coordinator. The study results will be kept in your record for at least six years or until after the study is completed, whichever is longer. At that time either the research will be destroyed or information identifying you will be removed from the study results at DUHS. There is a potential risk to confidentiality: if we learn of possible child abuse, neglect, or some other risk to a person under your direct care during the research, we will be required by law to notify the Durham Department of Social Services.

Your research records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System Institutional Review Board. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Only the summarized information and data resulting from this study may be presented at scientific meetings or published in a scientific journal. Your identity will always be kept private.

WHAT ARE THE COSTS?

There are no costs to you of being in this research.

WHAT ABOUT COMPENSATION?

You will receive a \$50 pre-paid gift card and a small, age-appropriate toy (valued at \$5) for your child to thank you for your participation.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Whether or not you participate in the research is completely up to you (it is voluntary). Your decision will not affect medical care or social services for you or your child in any way. If you decide to be in the research, you are free not to answer any questions for any reason.



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You may choose not to be in the study; or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal), but you must do this in writing.

Your decision not to participate or to withdraw from the study will not involve any loss of benefits to which you are entitled and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Dodge in writing and let him know that you are withdrawing from the study. His mailing address is *Center for Child and Family Policy, Duke University, Box # 90545, Durham, NC, 27708*. At that time, we will ask your permission to continue using all information about you that has already been collected as part of the study prior to your withdrawal.

If we change the research in any way that will affect you or your child, we will tell you about the changes. We might need you to sign a new consent form if there are changes in the research.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, or if you have complaints, concerns, or suggestions about the research, please call Dr. Kenneth Dodge, the director of the study, at (919) 613-9334.

For questions about your rights as a participant in research, or to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research, please call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.



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STATEMENT OF CONSENT

“The purposes of this research, procedures to be followed, and risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have more questions, to discuss problems, concerns, or suggestions related to the research or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time and that my withdrawal will not interfere with medical care or social services for myself or my child. I have been told that I will be given a signed copy of this consent form.”

Name of Participant
PLEASE PRINT

Signature of Participant

DATE

Name of Person Obtaining Consent
PLEASE PRINT

Signature of Person Obtaining Consent

DATE