

COVER PAGE

The Dedicated African American Dad Study

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Mother Informed Consent Document

Mother Consent Document

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Title of Study: The African American Non-resident Fatherhood Program

Sponsor: National Institutes of Health/National Institute for Nursing Research



Subject Information Sheet and Consent Form

Introduction

This form provides you with information so you can understand the possible risks and benefits of participating in this study, so that you can decide whether or not you want to be a part of this research study. Before deciding whether to participate in this study, you should read the information provided in this document and ask questions regarding this study. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate.

Why are you invited to participate in this study?

You are being asked to take part in this study because you are the mother of a child whose father is signing up to participate in the D.A.A.D. Study to improve his skills taking care of his child. Please take your time to make your decision and discuss it with your friends and family. Remember that your participation is completely voluntary. There is no penalty if you decide not to take part in this study or decide later that you want to stop participating in this research study. Your care at Rush University Medical Center will not be affected if you decide not to participate.

What is the purpose of this study?

The purpose of this study is to learn if participating in a skills building program will help fathers stay connected with their young children. As part of this program we would like some information about your child and about the ways their father is involved in the child's life. Fathers who sign up for this program will meet in groups with about 10-12 other fathers over 12 weeks. During that time there will be 9 meetings, 3 scheduled break-weeks, and a booster session to be scheduled 6 weeks after the groups end. The fathers will be randomized into either a Fatherhood Program or a Finance Program. Randomization is like flipping a coin to decide which group the father will participate in. We hope that the information fathers learn will help them have a good relationship with their child. You are being asked to complete an interview about your child at the beginning, middle and end of the study.

How many study subjects are expected to take part in the study?

We plan to have about 180 fathers and 180 mothers take part in this study and all of the fathers and mothers will be signed-up to participate by investigators from Rush. This is currently the only site for this study.

What will you be asked to do?

If you wish to be a part of this study:

1. You will need to read and sign the “Consent Form.” By signing this consent form you are letting us know that you have read about our project, understand that it is a research study, have had your questions answered, and that you agree to participate in this study. You will be given a copy of this form to keep.
2. Agree to your child’s father spending more time with him/her. This may mean that he takes your child out to do things with him/her or that he comes to your home to spend time with his child. You are not required to participate in outings with your child and his/her father but you are free to do so if you like.
3. After you sign the “Consent Form,” your participation will begin. You will need to complete an interview with a member of our study team that tells us about your child/ren before you can be a part of the study. We need this information to make sure that we know about your child’s relationship with his/her father. The survey takes about 20-30 minutes to complete. You will be asked to fill this survey out at the beginning, middle and end of the study.
4. Each time you will be interviewed by a member of the research team.

What will the father of your child do in the fatherhood group meetings?

The groups will meet for about 2 hours 12 times over the next 6 months. During these meetings trained group leaders will help fathers learn new skills that they can use while spending time with their child or help them learn ways to better manage their finances (depending which group they are selected randomly for (like with a flip of a coin)).

How long will you be in the study?

Altogether, you will be participating in the study for about 9 months.

What are the possible risks of the study?

There is a risk that if the father increases his contact with you and your child that there may be increased conflict between you and him. If this happens, we have a team of 3 professionals (clinical psychologist, mental health nurse specialist and social worker) who you can talk to; and who can help you connect with local community-based resources to get help with solving problems with your child’s father. If you would like more information on these services please contact Dr. Wrenetha Julion, the nurse in charge of this study. There will be no costs related to meeting with members of the study research team; however you will be responsible for any costs you have related to seeking counseling or obtaining help problem-solving with your child’s father.

This project has been approved by the Rush University Medical Center’s Institutional Review Board (IRB). The IRB is a special committee that reviews human research to check that the rules and regulations are followed. We developed a parenting program about 10 years ago, and we received very positive comments from the parents that participated in the program. If any additional risks to participation become known or if new information comes out that may affect your desire to stay in the study, we will let you know in a timely manner. If for any reason this project and, thus your participation is stopped, we will also let you know.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study, other than helping your child’s father learn new skills so that he can be a positive and consistent part of your child’s life. We do believe that children benefit when their fathers are positively and consistently involved in

their lives.

What other options are there?

Other than being a part of a parenting group through another agency or in the community, there is no alternative program being offered at this time. If you choose not to participate in the study, any programs that are being held in the community would still be available to you. If you chose not to be a part of the study, your child's father will not be able to sign up for the study. This is because your child's father needs to spend time with the child so he can practice what he learns and so he can have a good relationship with the child. Everyone who is a part of this study has the right to withdraw from the study at any time. Please contact Dr. Wrenetha Julion at 312-942-6272 if you would like to stop participating in the study. We will keep and analyze the data that we have already collected from you. This data will be analyzed without making your identity known.

What about confidentiality of your information?

Records of participation in this research project will be maintained and kept confidential as required by law. We will use a code number on all of your surveys. Other than this code number, there is no way your answers to the questions can be connected to you or your child. Your answers to questions about your child will be entered into a computer and looked at as part of a group of children whose father is participating in a skills building program. If the results of this project are published, your child's identity will not be made known. People who are in charge of the agency who gave us the money for this study, and The Rush Institutional Review Board (IRB) may ask to see the research to make sure that it is being done correctly and ethically, but this will be done without any loss of confidentiality. After five years, the information you have provided to us will have all identifying information removed from it and the records that link the information to you will all be destroyed. The data will then be kept indefinitely until it is determined that they can serve no further useful purposes.

To further protect the confidentiality of your data, we 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 will be necessary, however upon request of the NINR or other federal agencies 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. If you give your consent to a third party 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 and the confidentiality of your data.

Finally you should understand that the investigator is not prevented from taking steps including making reports to authorities to prevent serious harm to yourself or others. All members of the research team are required by law to report child abuse or neglect to the Department of Children and Family Services. In addition, if members of the research team have reason to believe that there is a threat of violence to you or others, we will also report that information to the appropriate authorities.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is entitled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

What are the costs of your participation?

If you choose to participate in the study, there are no additional costs to you other than the cost of your time. However if you decide to seek counseling or family therapy in order to solve problems with your child's father, we are not able to pay those costs for you.

What financial disclosure(s) apply to this study?

Research studies like this one are designed to determine whether the program affects father involvement in pre-school children. Rush University owns the patent on the program called Building Bridges to Fatherhood (BBTF) being studied. If research shows the program is effective, Rush University would receive profits from any sales and or licensing of the program.

It was determined that the additional payments to Rush were considered unlikely to affect your safety and/or the scientific quality of the study. This recommendation was given to the IRB for its review and approval of this study. If you would like more information, please ask Dr. Julion.

Will you be paid for your time?

You will get \$40 every time you complete the interview about your child and his/her father (\$120 total), as compensation for the time you spend being interviewed.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. We do not expect that you or your child will experience any injuries as a result of being in the study. However, Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

Whom do you call if you have questions or problems?

Questions are encouraged. If you have any concerns about this or anything else related to this project, or if you experience a research related injury, please call Dr. Wrenetha Julion, who is in charge of this project at (312) 942-6272. You may also choose to get out of this project at any time by calling Dr. Julion at (312) 942-6272. Dr. Julion is a teacher and nurse who works at Rush University Medical Center. If you have any questions about the rights of people who are a part of research studies at Rush please call the Rush Research and Clinical Trials Administration Office at 1-800-876-0722

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

Future Research

There may be other studies that come up in the future that are of interest to you. By checking the box below, you are agreeing that we may contact you in the future to see if you are eligible and willing to participate in future research.

Check here if you are interested in being contacted for future research.
 Check here if you are NOT interested in being contacted for future research.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT

Name of Subject

Signature of Subject

Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent

Date of Signature

Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).

SIGNATURE BY WITNESS/TRANSLATOR

(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator

Check here if a separate witness signature is not necessary.

Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator

Date of Signature

Check here if Principal Investigator obtained consent and a separate signature is not required.

