

MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **HERO Dads**. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Scott Wetzler, Ph.D. You can reach Dr. Wetzler's associate, the main contact for this study, at:

Traci Maynigo, Psy.D.
334 E. 148th St., 2nd Floor
Bronx, NY 10451
347-920-1655

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right-hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-4302253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg
#1002
Bronx, New York 10461

Support for this research study is provided by
the Department of Health and Human Services, an office of the Administration for Children and Families.

Why is this study being done?

The goal of this study is to determine what factors of parenting and relationship education improve family stability and relationship quality. You are invited to take part in a research program called HERO Dads. This research project will study the effects of a parenting and relationship education program on you. The program offers parents new skills to help them strengthen their relationships, become better parents, and improve their financial health. You are being asked to volunteer for a research study which is expected to last up to six months. The study will help the research team understand what kinds of services parents like you might need and want in the future.

If you meet program eligibility and agree to participate in the research study you will be enrolled in the HERO Dads program and will be given a schedule of workshops to attend. You will be asked to choose whether all services will be provided at the BronxWorks RF program site OR virtually via Zoom. You will attend a series of 16 workshops across 4 weeks. The workshops will cover topics such as improving communication in relationships, skills for resolving conflicts, parenting, and financial stability. The workshops will involve discussion and skill-building activities in a group setting. You will also be invited to participate in activities about special

topics that may be of interest to you and other parents, as well as other events offered for you and your family.

If you are not eligible to receive HERO Dads services, you will be given a list of other services providers and programs available in your community that you can contact on your own, and you will not be asked to be in the research study. If you enroll in the RF program and choose not to participate in the research study, you will still receive all RF services and there will be no penalty for choosing not to participate in the study.

Why am I being asked to participate?

You are being asked to participate in this study because you expressed interest in HERO Dads services. All services will be offered either at Montefiore Medical Center, located at 550 East 142nd Street, Bronx, NY 10454, or virtually via Zoom. The services will be randomized and you might be asked to do the services in person or virtually. Our program is aimed at serving families residing primarily in the Bronx or surrounding NYC area.

To be eligible:

- You must be 18 years or older
- You must have a non-custodial child who is 24 years or younger
- Your income must be below 200% poverty line

We anticipate enrolling 350 participants in this study annually.

What will happen if I participate in the study?

If you sign this consent form and agree to be in the study, information will be collected from you over the next six months. Before engaging in any of these activities we will ask for your permission. You may be asked to participate in data collection activities before beginning workshops, on the day you begin workshops, during the course of your participation in workshops, and after your workshop series concludes and at approximately 6 months after you first entered the HERO Dads program. You can refuse to participate in any data collection activities at any time, and still receive HERO Dads services. You can also decide that you do not want to be a part of the study at any time, and this decision would not affect your participation in the HERO Dads program in any way.

Data collection activities when you first volunteer to participate in the study

If you are found to be eligible and consent to participate in the HERO Dads Program and the research study, the program staff will ask you to complete questionnaires as part of the research data collection for this study. You will first complete a baseline information survey digitally on the nFORM website. This survey will ask you to provide basic background information about you. After completing the baseline information survey on nFORM, you will be asked to answer some other questionnaires. These forms include questions about your feelings toward your relationship with your child, how well you get along with your child's co-parent, and other topics related to how you are feeling about yourself and your family. In addition, you will participate in an intake interview with Montefiore staff on site or virtually via Zoom to discuss in detail more about your interest in services and potential barriers or elements that contribute to ongoing difficulties in your family. Your answers to these questions will help us learn if our HERO Dads services can have a positive effect on parent-child relationships and children's well-being. You may choose not to answer any of these questions at any time.

Lastly, the RF staff person will ask you to provide contact information, so that the researchers can get in touch with you for future data collection activities. You will be asked to provide the names and phone numbers of three people in your life who would most likely know how to contact you if you were to move or change telephone numbers in the next year.

Data collection activities six months after you first volunteered to participate in the study You will be asked to complete questionnaires at two additional time points after you first enter the study: at the end of your workshop series, and six months from when you entered the study. You will be asked about your how well you are getting along with your child and co-parent, your employment, and your feelings about how your children are doing. You will also be asked about your experiences with the program, like whether you found the services helpful, and the reasons why you were or were not able to attend the workshops. Your answers to these questionnaires will help the research team understand whether our services work for parents like you, help us to improve our program, and help others to build and improve other similar programs around the country.

How many people will take part in the research study?

You will be one of about **1,472** people who will be participating in this study.

Will there be audio and/or video recording?

If you enroll in the HERO Dads program, there may be times that workshop sessions are audiotaped or videotaped. Program supervisors may want to videotape workshops to make sure the program staff are doing a good job of engaging the individuals participating in activities. The audiotapes or videotapes may also be used by the research staff, so that they can understand how the program is operating and how it might be improved in the future. Your picture, voice, and first name will be on the audiotapes and videotapes, but no other identifying information, such as your full name and/or address will be on the tapes. Videotaping will not be used to monitor the discussions and/or actions of you or any participants in the workshop. These videotapes and audiotapes will not be shared with anyone outside of the research team and program staff without your permission. You may inform program staff if you refuse to participate in any recordings.

Information Banking (Future Use and Storage)

Research records will be kept in a secure manner, computer records will be password protected, and only research personnel authorized by the Principal Investigator will have access to these records. You will not be identified in any written or verbal reports with the following possible exceptions: the U.S. Office for Human Research Protections (OHRP), the Institutional Review Board (IRB) of the Montefiore Medical Center, and sponsors and collaborating groups may inspect your records. The sponsor of this program is the U.S. Department of Health and Human Services. Montefiore Medical Center will operate the RF program and oversee data collection activities as part of this research study. HERO Dads employees will collect information from participants. The information about you and/or your child will only be used for research purposes and other uses that you agree to. The information will not be used for any other purposes without your permission. This research information includes your answers to forms that you will fill out privately today, and your answers to survey questions collected by HERO Dads researchers when they contact you in the future. With respect to any data however, if keeping your answers private would put you, someone else, or your child in serious danger,

then the research and program staff will have to tell the appropriate authorities to protect you or the other person.

Will I be paid for being in this research study?

If you are enrolled in the HERO Dads program, you will be provided with monies for transportation and childcare costs you incur while participating in program activities. In addition, for completing initial intake and six-month follow-up after enrollment, you will receive an additional \$150 and transportation reimbursement for your contributions to the study.

Will it cost me anything to participate in this study? There will be no cost to you to participate in the study.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc. Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form. The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your researchrelated health information will be provided to you or your physician.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Are there any times you would not keep my data confidential?

If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself, our priority is to ensure your safety. For this reason, your personal information may be released as required by law or to ensure your safety.

If you give us information that you may hurt someone else, your personal information may be released as required by law to ensure your safety and the safety of those around you.

Are there any risks to me?

Your participation in this study will help us learn about how HERO Dads services help parents have better relationships with and improve the lives of their children. Your participation is greatly appreciated. However, if at any time, you desire to stop participation in the program and study, you are encouraged to do so with no consequence.

If you decide to participate, it is possible that you may be upset by some of the questions asked during the research data collection. You do not have to answer any questions that you do not want to answer and you may also stop being in the study at any time. If you withdraw from the study, the research team will use any information that we have collected up to that point. You will not be penalized, now or in the future, if you enter the study and withdraw later.

Questionnaire

You may feel uncomfortable answering questions about details regarding your relationship and family functioning. You can choose not to answer questions that make you feel uncomfortable. If you would like additional mental health or substance use resources, we can provide appropriate support and referrals to resources such as NYC WELL, which is a 24/7 hotline that can provide information about resources within the community. It can also be used in the event of a mental health crisis. English: 888-692-9355. Spanish: 888-692-9355 and press 3..

Are there possible benefits to me?

If you agree to participate in this study, there may or may not be any direct benefit to your relationship with your child, your individual well-being, or that of your children. The possible benefits of taking part in this study include improvement in your relationship with your child, improvement in your own well-being, and improvement in your children's well-being. In addition, the study will help improve services in the HERO Dads program and programs like it that may be offered to other parents. In this way, information learned from this study may benefit other parents and their children in the future.

What choices do I have other than participating in this study?

You may choose not to be a part of this study. Not choosing to participate in the research study has no impact on your receiving HERO Dads services. You will receive the same parenting and financial education services, as well as other services for your family, without being part of this study. Or, if you agree to participate in the study you may refuse to participate in any data collection activities or decide to stop being in the study at any time.

Are there any consequences to me if I decide to stop participating in this study?

No. Your participation in this study is voluntary. You may be a participant in it only if you wish, and you may withdraw from the study at any time. If you withdraw from the study, we will use any information that we have collected before then. You do not waive any of your legal rights by participating in this research study. Your treatment by doctors at the Montefiore Medical Center and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the study and withdraw later.

Can the study end my participation early?

Your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant

Signature of participant

Date

Printed name of participant

Signature of participant

Date

Printed name of the person conducting the consent process

Signature

Date