

Title: Supporting Healthy Relationships Program for FRAMEWorks  
(SHR FRAMEWorks)

NCT#: **NCT05367102**

ID: **2021-12751**

IRB Approval Date: **02/27/2025**

**MONTEFIORE MEDICAL CENTER****DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION****Introduction**

You are being asked to participate in a research study called **Supporting Healthy Relationships (SHR)**. 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. 148 St., 2 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 718-430-2253, by e-mail at [irb@einstein.yu.edu](mailto: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 relationship education improve family stability and relationship satisfaction and/or quality. You and your partner are invited to take part in a research program called Supporting Healthy Relationships (SHR). This research project will study the effects of a relationship education program on you and your partner. The relationship education program offers couples 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 couples like you and your partner might need and want in the future.

If you and your partner meet program eligibility and agree to participate in the research study you will be enrolled in the SHR program and will be given a schedule of weekly relationship education workshops to attend together. You will be asked to choose if you would like all services to be provided virtually via Zoom or to be provided in-person. You will attend a series of 10 workshops across 10 weeks. The workshops will cover topics such as improving communication in relationships, skills for resolving conflicts, and parenting children together. The workshops will involve discussion and skill-building activities in a group setting. You will also be asked to participate in activities about special topics that may be of interest to you and other couples, as well as other events offered for you and your family.

If you are not eligible to receive SHR services, you will be given a list of 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 SHR program and choose not to participate in the research study, you will still receive all SHR 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 SHR services. All services will be offered virtually via Zoom. Our program is aimed at serving families residing primarily in the Bronx or surrounding NYC area.

To be eligible:

- Both partners must be 18 years or older
- You and your partner must be in a committed relationship and living together
- Couples must be expecting and/or have a child under the age of 18 living in the home
- Income must be below 200% poverty line

We anticipate enrolling 350 couples 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 and your partner over the next six months. Before engaging in any of these activities with you and your partner we will ask for your permission. You and your partner 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 SHR program. You and your partner can refuse to participate in any data collection activities at any time, and still receive SHR 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 SHR program in any way.

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

If you and your partner are both found to be eligible and both consent to participate in the SHR Program and the research study, the program staff will ask you and your partner 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 and your partner. After completing the baseline information survey on nFORM, you will be asked to answer some other questionnaires in private. Your partner, if he or she also agrees to be part of the study, will also be asked to answer the same set of questions in private. These forms include questions about your feelings toward your relationship/marriage, how well you get along with your partner 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 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 relationship. You will also need to complete other surveys to further inform us of where you are with your relationship. Your answers to these questions will help us learn if our SHR services can have a positive effect on couples' relationships and their children's well-being. You may choose not to answer any of these questions at any time.

Lastly, the SHR 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 and your partner 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 relationship/marriage and how well you are getting along with your partner, 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 relationship education services work for couples like you, help us to improve our program, and help others to build and improve other relationship education programs around the country.

**How many people will take part in the research study?**

You will be one of about **2,944** people who will be participating in this study.

**Will there be audio and/or video recording?**

If you enroll in the SHR 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 couples participating 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. You and your partner's pictures, voices, and first names will be on the audiotapes and videotapes, but no other identifying information, such as your full names and/or addresses will be on the tapes. Videotaping will not be used to monitor the discussions and/or actions of any couples in the workshop, you, or your partner. These videotapes and audiotapes will not be shared with anyone outside of the research team and program staff without your permission. You and your partner 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 SHR program and oversee data collection activities as part of this research study. SHR employees will collect information from couples. The information about you, your partner, and/or you 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 SHR 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.

**Data Stored with Identification Linking Code**

We will store information about you in a "bank", which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy the information in the bank

but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

### INITIAL ONE (1) OF THE FOLLOWING OPTIONS

\_\_\_\_\_ I consent to have my information used for future research studies.

\_\_\_\_\_ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

### INITIAL YOUR CHOICE BELOW

\_\_\_\_\_ I consent to be contacted in the future to learn about:

\_\_\_\_\_ New research protocols that I may wish to join.

\_\_\_\_\_ General information about research findings.

\_\_\_\_\_ I do not want to be contacted at all.

### Will I be paid for being in this research study?

If you and your partner are enrolled in the SHR 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 research-related health information will be provided to you or your physician.

**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 relationship education services help couples have better relationships and improve the lives of their children. You and your partner's participation are greatly appreciated. However, if at any time, you or your partner 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 LIFENET, 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: (800) 543-3638. Spanish: (877) 298-3373.

**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 partner, your individual well-being, or that of your children. The possible benefits of taking part in this study include improvement in your couple relationship, improvement in your own well-being, and improvement in your children's well-being. In addition, the study will help improve services in the SHR program and programs like it that may be offered to other couples. In this way, information learned from this study may benefit other couples 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 SHR services. You will receive relationship education and other services for couples, 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 names of participants	Signatures of participants	Date
_____	_____	_____
Printed name of the person conducting the consent process	Signature	Date