**EMERGENCY DEPARTMENT HEALTHCARE EDUCATION ASSESSMENT AND RESPONSE FOR TEEN RELATIONSHIPS (ED-HEART): A PILOT FEASIBILITY STUDY**

**ADOLESCENT CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY AT CHILDREN'S MERCY HOSPITALS**

## SUMMARY

We are asking you to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your regular medical care or your relationship with Children's Mercy.

This research study is being done to better understand how we can support healthy dating relationships for teens and provide resources for teens experiencing dating violence. "Dating violence" includes unhealthy relationship behaviors like name calling, controlling what your partner does, and things like forcing your partner to do sexual things they don't want to or hitting or kicking your partner.

Some teens in the study will receive the ED-HEART (Emergency Department Healthcare Education Assessment and Response for Teen Relationships) intervention. The goal of the ED-HEART intervention is to help teens have healthy relationships and connect teens to resources for dating violence.

## WHO IS DOING THIS STUDY?

A study team led by Dr. Kimberly Randell is doing this study with the help of other health care professionals. Funding for this study comes from the National Institutes of Health. The study team will not receive any personal payment because of your decision to participate.

## WHY IS THIS STUDY BEING DONE?

This study is being done to learn about how the ED-HEART intervention might work and if it's a good idea to use the intervention as part of how we take care of teen patients in the emergency room (ER).

## WHO CAN BE IN THIS STUDY?

We are asking 174 14-19-year-old teens to be a part of the research study at Children's Mercy.

## WHAT WILL HAPPEN TO ME IN THIS STUDY?

If you choose to be in this study, then you will be "randomized" into one of two groups described below. This means that you are put into a group by chance (like flipping a coin). There is no way to know which group you will be assigned to. You or your doctor cannot decide what group you will be in.

**Group 1 and Group 2**:

- Both groups will get a handout about resources for teens. If your parent is here with you today, they will get an information sheet about the study. You will get a copy of this form.
- We will ask both groups to take a survey on an iPad while in the ER. The survey will ask about your thoughts about and experiences with dating and relationships.
- We will email, text, call, and/or use your social media handle 6 weeks after the ER visit to make sure we still have the best contact information for you.
- We will ask both groups to take a follow up survey 3 months after your ER visit.
    - A reminder contact about the upcoming 12-week survey will be sent to you at 11 weeks via your preferred method of contact.
- We will ask for your contact information (email address, mailing address, phone number, and/or social media handle) so that we can send the link to the follow up survey in 3 months. We will send the survey link by email and/or text. We will call you or direct message you to remind you about follow up survey if you don't take the survey after the link is sent.
- The study team will get information from your medical record. We will look at the treatment you got at your ER visit and your insurance type. We will use your medical record to see if you have scheduled appointments or are admitted to Children's Mercy during the 6 week and 12 week follow-up windows and the study team may approach you at this time to offer the opportunity to complete the survey.

**Group 2:**

- If you are in Group 2, you will get the ED-HEART intervention during your ER visit:
    - Someone from the study team with spend some extra time with you to talk about dating, healthy and unhealthy relationships, and ways we can help teens experiencing dating violence.
    - We will talk to you about resources you can use while in the ER. If you would like to use these resources, your ER doctor or nurse practitioner may talk to you to make sure these resources are a good fit for you. You may choose not to use any of these resources. The choice is up to you.
- We will audio record the conversation you have with the study team during the ED-HEART intervention. We will use the recording to make sure we are doing the ED-HEART intervention right.
- While you are still in the ER, you will be asked to complete a survey on an iPad. This survey will ask about what you think about ED-HEART and your thoughts on dating.

We will know if you complete the study surveys and the 6-week check-in. But we will not know how you answered the survey questions. Your name will not be linked to your answers.

Being in the study will take up to one hour for teens in Group 2 and up to 40 minutes for teens in Group 1. For both groups, the 3-month follow-up survey will take up to 30 minutes.

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**WHAT ARE THE RISKS OF THE STUDY?**

There is minimal risk for being in this study. These risks may include:

Mandated reporting

- If you are less than 18 years old:
    - There are a few situations where confidentiality will not be kept. If you tell the study team that you or another teen or child has been hurt or is in danger, the study team will need to talk to the team taking care of you in the ER today and someone will speak to you while you are in the ER. If you verbally tell the study team about an unhealthy dating relationship you are or have been in, you will have the opportunity to talk to someone today about ways to deal with this relationship if you want. If the study team has concerns that you are in a severely abusive relationship or that you might not be safe in this relationship, they will need to tell your healthcare team and someone will

speak to you about this today. To make sure you are safe, someone may also need to speak to your parent or guardian about it. CMH personnel, as mandatory reporters, are required to report physical or sexual abuse to the authorities.

- If you are 18 years of age or older:
    - If you verbally tell the research team about suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect, CMH personnel, as mandatory reporters, are required to report it to the authorities.

Feeling uncomfortable:

- There is a chance that some of the questions may make you feel uncomfortable or embarrassed. You don't have to answer those questions if you don't want to. You can stop being in the study at any time. If you want to talk to the social worker today, you can let the study team or your ER team know.

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**WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?**

There may be direct benefit to you from being in this study. Possible benefits may include receiving the Teen Resource List and, if you are in Group 2, learning about the resources available in the ER.

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**WHAT ABOUT EXTRA COSTS?**

You will not have to pay anything extra if you are in this study. The Study sponsor will pay for any tests and medications given to you today that are a part of this study. Your insurer will be responsible for other costs. You will be responsible for any costs your insurer does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurer.

You may incur costs related to text messaging and/or data use on your cellular phone.

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**WHAT ABOUT CONFIDENTIALITY?**

If you decide to be in this study, your contact information will be collected. This includes your name, email, and phone number.

We will use a study number (instead of your name) to help protect your privacy. If you choose to use some reproductive and sexual health resources, such as testing or medication, your health information will stay within Children's Mercy Hospital medical record system like normal. We may take general notes about the visit that will not have any personal health information (PHI).

Your confidentiality will be protected to the greatest extent possible. To help minimize the risk to privacy, all information collected will be kept confidential among the study team and be recorded on an encrypted secure server through password-protected computers. There also is a risk to confidentiality when using the internet.

By providing your email or phone number, the study team may communicate with you about the study check in and follow up survey, send copies of assent/consent forms and any other non-clinical, study related communication. Please be aware of the following:

- Corresponding through electronic communication methods is not a secure method of sending information and others may be able to access the information sent.
- The information may not be secure if storing or viewing the permission/assent document on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena.
- Information that is sent electronically may be kept on the Hospital's or your service provider's (Google, Yahoo, MSN, etc.) network servers. Unlike paper copies, e-copies delivered directly to your PED may not be able to be permanently removed.
- The Hospital is not liable for any security breaches of your information sent electronically.

There are a few situations where confidentiality would not be kept (if you verbally tell us that you or another teen/child has been hurt or is in danger). This includes physical and sexual abuse or other abuse you may have experienced. If you choose to talk to the study team about an unsafe or abusive situation, this information will be reported to the appropriate organizations and hospital personnel.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide you as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your child’s information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

We will collect information needed to provide you with gift cards after study participation. This includes your name, address, and phone number. This information is needed for tax purposes related to compensation only. This information is not connected to your study data and cannot be used to link you with your study data.

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**WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?**

Instead of being in this study, you may choose not to be in the study. Whatever you choose will not affect your care today in the ER.

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**WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?**

You may get up to $50 if you complete all parts of this study. We will provide you with a gift card. This gift card can be used almost anywhere. Below is the payment schedule:

| Today’s visit | 6-week check in | 3-month follow-up survey |
|---|---|---|
| $20 | $5 | $25 |

If the total value of payments provided to you or your child from Children's Mercy Hospitals totals more than $600 each in any calendar year, the hospital must report this to the IRS on a Form 1099 with the recipient's social security number (SSN) or individual tax identification number (ITIN). You will receive a copy of this tax form. Accepting payment for taking part in the study may affect eligibility for Medicaid or other programs.

## WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. You do not have to be in this study to receive medical care. If you choose not to be in this study or withdraw from this study, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you withdraw from the study early for any reason, the information that already has been collected will be included in the study database. No further information will be collected for the study.

## WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Kimberly Randell is in charge of this research study. You may call Dr. Randell at (816) 302-3503 with questions at any time during the study. You may also call Anne Kleinwolterink, the study coordinator, at (816) 802-1487 with any questions you may have.

You may also call Children's Mercy Hospitals' Pediatric Institutional Review Board (IRB) at (816) 731-7474 with questions or complaints about this study. The IRB is a committee of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

## ASSENT/CONSENT OF PARTICIPANT

Your signature means you agree to the following statements:
I have had a chance to discuss the study and ask questions. My questions have been answered.
I understand the purpose, the required procedures, risks and benefits involved if I participate in the research.
I understand that I do not have to be in this study.
I know I can decide to quit the study at any time.
I agree to be in the study.

Signature of Participant

Date

Print name of Participant

## STUDY PERSONNEL

Your signature means you have confirmed that assent/consent of the adolescent, as applicable, has been obtained.
I have explained the purposes, procedures, and risks involved in this study in detail to the participant.
I have answered all questions.
I attest that, in my judgement, the participant possesses the capacity to give informed assent/consent freely.
I have confirmed the agreement of the participant and obtained their signature documenting that agreement.

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|---|---|---|
| Signature of Person Obtaining Permission/Assent | Date | Time |

Print Name of Person Obtaining Permission/Assent