

Implementation of Alcohol Screening, Brief Intervention, Referral to Treatment Policies in Pediatric Trauma Centers

NCT03297060

Consent Document approved by Lifespan - Rhode Island Hospital IRB 1

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Approved consent document on following pages

Lifespan Affiliate Site where research will be conducted

☒ Rhode Island Hospital
☐ Bradley Hospital

☐ The Miriam Hospital
☐ Newport Hospital
☐ Gateway Healthcare

**Agreement to Participate in a Research Study
And Authorization for Use and Disclosure of Information**

008917
Committee #

Name of Study volunteer

***Implementation of Alcohol Screening, Brief Intervention, Referral to Treatment Policies in
Pediatric Trauma Centers: Participating Center***

Your child is being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to allow your child to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what your child will be expected to do if they participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for your child.

If you decide to allow your child to be in the study, you will be asked to sign an agreement which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. You will be given a copy of this form to keep.

Federal and Lifespan institution rules require that if your child is 8 years or older, the "assent" (agreement) of your child be obtained by the researcher before your child may participate in this study. Your child must sign the consent form as well. You will be given a copy of the signed consent form to keep.

1. Nature and Purpose of the Study

Your child is being asked to take part in a research project so we can better understand how nurses, social workers and doctors within pediatric hospitals talk to their patients about alcohol and drug use. Those asked to participate are 12-17 years old and currently admitted to the hospital for an injury. We expect to enroll up to 1200 patients across ten hospitals into this study, with up to 120 enrolled at this institution. This study is sponsored by the National Institute of Alcohol Abuse and Alcoholism.

2. Explanation of Procedures

This study will involve the completion of a brief survey using a computer or by phone about one month from now to collect information about any alcohol or drug screening and related services your child may have received during or after their hospital stay. Today, you and your child will be asked to

provide contact information so that we can reach your child to complete this survey. This information will take 5 minutes to collect and will not interfere with your child's clinical care. About one month from now research staff at Hasbro Children's Hospital in Providence, RI (who is conducting the follow up surveys for all sites) will contact your child and ask them via email or text message to complete a brief (5-10 minutes) survey using the internet. If your child cannot access the internet, we can telephone them and do the survey over the phone. Your child's answers to the questionnaire will not be shared with you. Your child will receive a \$20 gift card for completing this survey. We will also review your child's medical records from this hospital stay only to see if any alcohol or drug screening and related services were provided.

Costs for participating in this study: There are no additional costs to participating in this research. There will be no additional 'research only' services performed only because they are participating in this research study. All services your child will receive during this research study are considered "routine clinical services" that your child would have received even if they were not in the research study. Examples are alcohol and drug screening and any related services. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information: If you have any questions about this study, they can be directed to the study doctor Dr. Michael Mello at 401-444-6684.

3. Discomforts and Risks

The risks to this study are considered minimal. These questionnaires are commonly used during research and clinical practice. Your child may experience some emotional distress answering questions about their hospital stay. Your child does not need to answer any questions that make him/her too uncomfortable.

4. Benefits

Your child may not receive any benefit from participating in this study. However, by completing this survey your child will help us to better provide alcohol and drug screening and related services within the hospital.

5. Alternative Therapies

If you do not choose to participate in this study, your child will not receive any surveys and will receive standard clinical care.

6. Refusal/Withdrawal

It is up to you whether you want your child to be in the study. You are not required to enroll your child or participate. If you decide you want your child to participate, you can always change your mind and remove them from the study at any time. If you decide not to have your child be in the study, or if you remove them later, your child will still be able to get the health care services they would normally get. If you enroll your child but later on the researcher or your doctor feels being in the study is no longer good for your child, they may choose to take your child out of the study before it is over. If new information becomes available that might change your mind about whether you want your child to stay in the study the researcher will share this information with you as soon as possible.

You have the right to change your mind at any time regarding your child participating in this study. If you decide to have your child quit the study please tell the head researcher Dr. Michael Mello at 401-444-6684.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If your child is injured by a medical treatment or procedure they would have received even if they were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If your child does experience a research injury, Lifespan or the study doctor can arrange medical treatment for them. Such treatment will be paid for as described below.

If you have insurance and your child has a research injury that is not covered by the study, it is possible that some or all of the cost of treating your child could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you or your child have any complaints about your child's participation in this study or would like more facts about the rules for research studies or the rights of people who take part in those studies, you may contact Janice Muratori, anonymously if you wish, in the Lifespan Office of Research Administration, at 401-444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information

There are two laws that provide ways to protect confidential information about your health. One known as "HIPAA" (Health Insurance Portability and Accountability) provides national standards for the electronic exchange, privacy and security of the information usually contained in your medical record. The second referred to as a Certificate of Confidentiality protects the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive health related research.

Personal Health Information is also called a "medical record". Your child's medical record is considered confidential. It is protected under the privacy laws called "HIPAA". This protection is not absolute. There are some times that medical records can be turned over without your written permission. In some cases, medical records can be subpoenaed. For example, any of the following groups can subpoena medical records if they have a good reason: an insurance company, government or attorney representing another person. All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

Protection of your medical record under HIPAA

There are federal regulations that give you the right to know:

- Who will be able to access your child's medical record information
- Why they can access it.

The health information we collect from your child in this study is called "data." Some of it may identify your child. The data in this study includes: demographic information such as age, gender, date of birth; contact information; results from questionnaires and medical record as described earlier. We will keep the data from this study until we are done working with it. When the data is no longer needed, it will be destroyed.

We will make every effort to keep the data in this study private. We will do this by keeping your data labeled with only a study id number, not your child's name. The name-number code will be kept locked up. This way no one outside the research team can look up your child's data. We will keep information that identifies your child in a separate place from your child's data. Study data that is kept on computers will be password protected.

Who may use or see your health information?

By signing this form, you are letting certain people use or see your child's data. This means that the research team at Hasbro Children's Hospital can use your child's data for this study and that the research team can show or give your child's data to others involved in the study.

This study is reviewed every year by groups that watch out for the safety of people in research studies: They also watch out to make sure the study is done right. These groups are allowed by law to look at your child's study data so that they can do their job. Also, any agency that has given money to do the study can look at your child's research record and any medical records held by the hospital may be used and released for research purposes. The following people or companies might use, release or receive such information:

- The research team: The researcher and their support staff from the enrolling institution and Hasbro Children's Hospital in Providence, RI (who will be doing the follow-up contact for the study);
- The study sponsor: National Institute on Alcohol Abuse and Alcoholism;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights;
- The hospital's IRB staff responsible for reviewing, approving and administering research activities
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

Do I have to let you use my data to be in the study?

You have the right to refuse to sign this form and not allow your child to participate in the research. Your refusal would have no effect on your child's treatment, charges billed to you, or benefits at this health care site. If you do not sign, your child will not be able to enroll in the research study.

You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Protection of your research record under the Certificate of Confidentiality

When a Certificate of Confidentiality is issued, then the study doctor cannot be forced to give out information that tells who you are or your child is. Certificates of Confidentiality are issued by the National Institutes of Health. They are used to protect research information that identifies you and your child. With a Certificate of Confidentiality, information that identifies you and your child cannot be released due to a court order or other means. This allows the study team to refuse to release information about you and your child in legal matters. This includes any legal matters that are: Civil, Criminal, Administrative, Legislative, Other proceedings. It includes matters at the federal, state, or local level.

Certificates of Confidentiality may be granted for studies collecting information that, if released, could have negative effects for participants (i.e. found guilty of a crime) or cause people in the study to lose money, their job, health insurance or reputation.

Below you will find more information about the protection of your child's medical records, protection of information you provide for this study and the limits on this protection. All of your child's records from this study (research records) will be maintained separately from your child's medical records. If you decide to permit your child to take part in this research study, your child will be asked to give us information about alcohol and other drug use. A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your child's privacy. This Certificate means that the researchers cannot be forced to disclose research information that may identify you or your child, even by court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for research information that would identify you or your child, except as explained below. This Certificate does not mean the government approves or disapproves of our project.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: If we see (learn) something that would immediately endanger you, your child, or others, we may discuss it with you, if possible, or seek help. If the researchers learn about your child's intent to do serious harm to him/herself or others, however, they will take steps to protect the person(s) endangered even if it requires telling the healthcare providers caring for your child in the emergency department or other authorities without your permission - but we would only disclose information to the extent necessary to prevent harm to the person(s) believed to be endangered.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing

information about yourself, your child, or your involvement in this research. Hospital staff outside of the research team (i.e. social workers) will not know if you are participating. If an insurer, employer, or other person obtains your written consent to receive such information, then the researchers may not use the Certificate to withhold that information. This means that you and your family must actively protect your own privacy by not sharing information about your participation.

If after you have signed this form you have any questions relating to your child's rights, please contact Janice Muratori in the Office of Research Administration, 401-444-6246. For more detail about privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

SIGNATURE

I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, AND I GIVE PERMISSION FOR MY CHILD TO PARTICIPATE IN THIS RESEARCH STUDY.

<p>This informed consent document expires on <u>4/25/2022</u>. DO NOT sign this document after this expiration date.</p>

The Researcher is required to provide a copy of this consent to you.

Signature of parent/legal guardian*

Date and Time when signed

Signature of parent/legal guardian*

Date and Time when signed

I AGREE TO PARTICIPATE IN THIS STUDY

Signature of study volunteer (child)*

Date

Age of study volunteer (child)

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT ABOVE BY THE PARENT/GUARDIAN OR AUTHORIZED REPRESENTATIVE

Parent/Guardian Initials _____

Signature of witness (required if consent
presented orally or at the request of the IRB)

Date

Signature of Translator

Date

IF STUDY VOLUNTEER IS UNABLE TO SIGN OR EXCEPTION TO ASSENT IS
SOUGHT, PLEASE EXPLAIN:

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PARENTS AND
STUDY VOLUNTEER, THE NATURE AND PURPOSE, PROCEDURES AND THE
POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

Signature of researcher or designate

Date

and Time when signed

* If signed by agent other than parent and study volunteer, please explain below.

