Principal Investigator: Marian Betz, MD, MPH
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Study Title: Assisting in Informing Decisions in Emergency Departments (ED-AID) Study

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about home safety when there is a risk of suicide in the home.

You are being invited to volunteer for this research study because you are currently being treated in the Emergency Department for thoughts or behaviors related to self-harm or suicide.

Up to 70 people will participate in the study at three different hospitals around Colorado.

What happens if I join this study?

If you join the study, you will receive the standard care which is provided in the Emergency Department for patients with suicide risk. In addition, you will be asked to answer a questionnaire about yourself. You will then be randomly assigned to review one of two different sets of information on a tablet. You will review the tablet while in the Emergency Department. After reviewing the information, you will be asked questions about your opinion on what you read. In one week, a study staff member will call you and ask another series of questions about how you have been feeling and what you have done since your visit in the Emergency Department today. Participation in the Emergency Department will be approximately 60 minutes. Follow up will be done over the phone, and will last approximately 20 minutes.

If you decide to participate in this study, you are agreeing to:

1. Review information on a tablet and answer a series of questions about what you read.

2. Complete an interview over the phone with a research staff member one week from today.

3. The researchers will review your medical records for the next 3 months.

4. The researchers will review publicly available databases, like your state's vital statistics registry (a document created by the state that tracks important health indicators, like births, deaths, and cause of death), to collect information about you.

5. Identifying a family member of friend that may be interested in participating in the study as well. However, if you cannot identify a family member or friend, you may still enroll in the study.

How We Decide Which Study Group You Will Be In

This study will have 2 different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will view different versions of information about ways to prevent suicide. Both groups will still receive regular care in the Emergency Department.

You Will Not Know Which Group You Are In

You will not know which treatment group you are in. Neither will your Emergency Department providers. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions. However, we can give this information out if you have an emergency.

If you are in another emergency situation, make sure you tell the emergency staff about this study. They can contact us, and we will give them any relevant information.

What are the possible discomforts or risks?

The procedures of this study pose minimal medical or psychological risks. There is a small risk of accidental breach of private information. We will take every possible step to ensure your privacy. Although there is no way to guarantee 100% that your privacy will be maintained, your privacy is very important to us. Your research records will be confidential to the extent possible. In all records, you will be identified by a code number and your name will be known only to the researchers and staff involved with the study. Your name will not be used in any reports or publications of this study. However, the study sponsor, the National Institute of Mental Health, and/or their representatives, the Colorado Multiple Institutional Review Board and/or their representatives may inspect your medical records that pertain to this research study. We will not allow them to copy down any parts of your identifiable information (e.g. your name) or take any of your identifiable information from our offices.

In this study, we will ask you questions about access to firearms. This information will not be shared with anyone outside of the study, including law enforcement or other authorities, and it will not be recorded in your medical record.

Participating in this research study will not offer any protection from future suicidal risk.

The study may include risks that are unknown at this time. We will inform you if unexpected risks are found during the course of the study.

What are the possible benefits of the study?

This study is designed to learn more about how to help people who may be at risk of suicide. The information you will view during the study may enhance the care you receive in the Emergency Department. The follow-up telephone call in a week may also provide some additional support to you. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomfort and risks.

Are there alternative treatments?

Participation in the study is voluntary. If you decide not to participate, you will receive the standard, usual care in the Emergency Department for a patient being evaluated for suicide risk. If you decline to participate, it will not impact or change your clinical care today.

Who is paying for this study?

This research is being paid for by the National Institute of Mental Health (NIMH). It is important to know that payments for participation in a study is taxable income.

Will I be paid for being in the study?

You will receive a $25 gift card after completing the follow-up phone call one week from today.

Will I have to pay for anything?

NIMH will provide the study at no cost to you. Procedures that are done only for the study will not be billed to you or your insurance company. You or your insurance company may be billed for any standard medical care given during this research study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If you are currently on a mental health ("M1") hold, you still maintain the full right to refuse and determine if you would like to participate or not.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

Who do I call if I have questions?

The researcher carrying out this study is Marian Betz, MD, MPH. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Betz at 720-848-6770.

You may have questions about your rights as someone in this study. You can call Dr. Betz with questions. You can also call the Colorado Multiple Institutional Review Board (IRB). You can call them at 303-724-1055. If you ever are feeling like you may hurt yourself, or are having thoughts of suicide, you can call the Colorado Crisis Line 24/7 at 1-844-493-8255. You will be given a copy of this form to keep.

A description of this clinical trial will be available on http://www.Clinical Trials.gov. 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 Website at any time.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital
- Denver Health and Hospital Authority
- Memorial Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's

Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Marian Betz, MD, MPH
University of Colorado Denver
12401 E. 17th Avenue, Mail Stop B-215
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- National Institute of Mental Health who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

One time per year we will provide the Colorado Department of Public Health and Environment with information (name, date of birth and Street Address) about all study subjects in order to assess subjects' vital status.

Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we have to report that to the police or local emergency services. Also, if we get a court order to turn over your study records, we will have to do that. While in the Emergency Department, if you share information with us that would be relevant to the safety of your clinical care, we have to share that information with your attending provider.

You have the right to request access to your personal health information from the Investigator.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Psychological tests
- Alcoholism, Alcohol or Drug abuse

What happens to Data that is collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data is given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data specimens collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____