**Official Title:** Brief Suicide Intervention for Youth in Juvenile Detention Settings

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Duke University Health System

**Consent To Participate In A Research Study (Open Trial)**
***Brief Suicide Intervention for Youth in Juvenile Detention Settings V.1.31***

SUMMARY

The purpose of this study is to learn how we can better help youth involved in the juvenile justice system. A small proportion of youth who are admitted to juvenile detention facilities start to feel so upset that they have thoughts of wanting to hurt themselves. We have developed a brief new intervention that can provide support to youth who feel badly before they are evaluated by a mental health provider from the community. For youth who receive the new intervention, we ask your permission to collect information about the helpfulness of the approach, and to contact you two months after your youth is discharged from the facility to see how s/he is doing, and to see if you have been able to obtain needed treatment. The information we collect will be obtained during the intervention, one and two weeks after the intervention, and at the follow-up assessment. Risks include potential loss of confidentiality and potential discomfort with completing the questionnaires. Benefits include close monitoring of suicidal thoughts and behaviors. Participants (parent or caregiver only) will be compensated for completing parts of the study.

Your child is being asked to take part in this research study because your child is involved in the juvenile justice system. This research study is voluntary and includes only people who choose to take part. Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

## WHO WILL BE THE DOCTOR IN CHARGE OF THIS STUDY?

If you decide to have your child participate, ***Dr. David Goldston*** at Duke University will be the psychologist in charge of the study. He will be in contact with your child's health care providers during the juvenile detention stay and prior to the last follow-up assessment, if needed.

Please tell the psychologist in charge of this study (***Dr. David Goldston***) or study staff if your child is taking part in another research study.

A grant from the National Institutes of Health (NIH) is sponsoring this study. Portions of ***Dr. David Goldston's*** and his research team's salaries are being paid by this grant.

Department of Public Safety staff are not leading this research project. However, staff will help in obtaining consent and collecting data to evaluate the intervention in the study.

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## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn how we can better help youth involved in the juvenile justice system who feel so badly that they have thoughts of wanting to hurt themselves. In this study, juvenile detention staff will be trained in a strengths-based intervention to help youth who are experiencing thoughts of suicide or about hurting themselves. This study is being done to see if the intervention helps to prevent future thoughts of suicide among youth in the juvenile justice system who have experienced suicidal thoughts.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 10 to 20 people in juvenile justice facilities in North Carolina will take part in this study.

## WHAT IS USUAL CARE FOR YOUTH IN CRISIS?

A small proportion of youth may have times when they are feeling so upset that they have thoughts of wanting to hurt themselves. If your child is thought to be at risk for suicide, your child will be monitored closely and will receive an evaluation by a licensed mental health professional within 24 hours. In addition, direct care staff will provide a brief intervention to help support your child during this stressful time until s/he can be seen for an evaluation by a mental health provider from the community. This intervention will also include up to two brief phone calls with you after your child leaves this facility to provide support and see if your child has any needs for additional services. This intervention will be provided to all children at the facility who are thought to be at risk for suicide.

## WHAT IS INVOLVED IN THIS STUDY?

If you agree to allow your child to be in this study, you will be asked to sign and date this consent form. We will only collect information from families who consent, and from youth who are experiencing crises and need help while in the facility. Youth who assent to the study and reach their 18th birthday while they are enrolled in this study will be asked to sign a new consent form once they turn 18.

The purpose of this research is to help us evaluate the helpfulness of the approach used by staff and facilities when youth are in crisis. You and your child have the choice of allowing the study team to use information gathered from your child to help improve and evaluate our approach, and to participate in a follow-up phone call, during which we will ask some questions about the helpfulness of this approach, and how it can be improved. As part of this evaluation, your child will answer some brief questions about how they are feeling if they receive the evaluation. These questions will be asked again one week, and then two weeks later if they are still in the facility. We also will consult with juvenile justice staff with access to health records to learn more about any times when your child needed assistance while in the facility because of how upset they were.

In the month after your child has left the facility, we will call you to briefly check-in with you regarding your son or daughter and see if there are any additional supports you might need.

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Two months after your child leaves the juvenile detention facility, a member of the study team will call your family to follow-up and your child will be asked to complete questionnaires over the phone. If your child does not receive the intervention or answer the study questions while at the facility, you and your child will not be asked to complete a follow-up phone call.

**HOW LONG WILL I BE IN THIS STUDY?**
Your child will be in the study while in the facility and for the next two months. Over the course of this time, they will be asked to complete questionnaires 3 times. The questionnaires take about 30 minutes to complete. At the end of the two months, we will also contact you and your child by phone for a brief interview, which should take no more than 30 minutes.

You and your child can choose to stop participating at any time without penalty or loss of any benefits to which your child is entitled.

**WHAT ARE THE RISKS OF THE STUDY?**
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You or your child may refuse to answer any of the questions and may take a break at any time during the study. You or your child may stop participation in this study at any time. The information shared by your child may result in increased supervision and monitoring to help ensure their safety, and to better address their needs when upset.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
If you agree to allow your child to take part in this study, your child may benefit from increased monitoring of suicide risk, or from sharing of information with clinicians caring for your child. We hope that in the future the information learned from this study will benefit other youth involved in the juvenile justice system.

**WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research may involve some loss of privacy. We will do our best to make sure that information about your child is kept confidential, but we cannot guarantee total confidentiality. Your child's personal information (such as names, age, gender, race and ethnicity, contact information, information about any crises, answers to questionnaires) may be viewed by individuals involved in this research and the care of your child. This includes people collaborating, funding, and regulating the study, as well as juvenile justice clinical staff taking care of your child during a crisis. We will share only the minimum necessary information in order to conduct the research, keep your child safe, and help obtain care for your child. Your child's personal information may also be given out if required by law.

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Some of the information we are asking to use and share is called "Protected Health Information (PHI)." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. You should know that confidentiality will be broken if youth (a) indicate plans to harm themselves, (b) indicate plans to harm someone else, (c) disclose previously unreported abuse according to the state of North Carolina, and/or (d) disclose plans to escape or avoid supervision at the facility. This information will be immediately reported to Department of Public Safety staff so we can keep your child safe.

As part of the study, results of your child's study-related procedures may be reported to NIH and its affiliates. In addition, your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of NIH, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your child's research record, they may also need to review your child's entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information shared with an insurer, medical care provider, or any other person not associated with the research or juvenile detention facility, you must sign a release of information form to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to your child or others. Information about thoughts of

suicide or self-harm collected as part of this study will be provided to mental health counselors involved in your child's care.

The study results will be retained in your child's research record for six years after the study is completed or until your child reaches the age of 21, whichever is longer. At that time either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS. Any research information in your child's medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's name or other personal identifying information (such as birthdate or address) will not be revealed.

Some people or groups who receive your child's health information might not have to follow the same privacy rules. Once your child's information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your child's private information with anyone not involved in the study, the federal law designed to protect your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**HOW WILL INFORMATION FROM THIS STUDY BE SHARED IN THE NIMH DATA ARCHIVE?**

Information from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA allows researchers studying mental health and substance use to collect and share information with each other. All personal information about research participants such as name, address, and phone number will be 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 information about your child's health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to this information 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 find better interventions. NIMH will also report to Congress and

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on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about any information 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://nda.nih.gov.

**HOW WILL A DESCRIPTION OF THE STUDY BE SHARED WITH CLINICALTRIAL.GOV?**
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time.

**WHAT ARE THE COSTS TO YOU?**
There are no costs to participation.

**WHAT ABOUT COMPENSATION?**
As parents or caregivers, you will receive $30 compensation for participation in the follow-up assessment if your child receives the intervention and is enrolled in the study. Your child will not be compensated for their participation in the study.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of his/her participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your child's Duke physicians to provide monetary compensation or free medical care to your child in the event of a study-related injury.

For questions about the study or research-related injury, contact ***Dr. David Goldston*** at [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to allow your child to be in the study, or, if you agree to allow your child to be in the study, you may withdraw your child from the study at any time. Your child also can decide to stop participating in this study at any time. If you withdraw your child from the study, no new data about your child will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to consult with juvenile justice staff with access to health records to learn more about the context of the event. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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Your decision regarding whether or not to provide permission for your child to participate in this study (or withdraw from the study) will neither help nor harm your child's court case or have an impact on the release date, length of stay, terms of supervision, medical care, or general living conditions while in juvenile detention. The decision to participate will also not involve any penalty or loss of benefits to which your child is entitled and will not affect your child's access to health care at Duke.

If you do decide to withdraw your child, we ask that you contact Dr. David Goldston in writing and let him know that your child is withdrawing from the study. His mailing address is: Duke Child and Family Study Center, 2608 Erwin Road, Suite 300, Pavilion East, Durham, NC 27705.

We will tell you and your child about new information that may affect your child's health, welfare, or willingness to stay in this study.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you or your child have problems, concerns, questions or suggestions about the research, contact ***Dr. David Goldston*** at [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays.

For questions about your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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**STATEMENT OF CONSENT**

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed Name of Child:

_____
Printed Name of Parent/Guardian:

_____ _____ _____
Signature of Parent/Guardian Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

_____ _____ _____
Witness Date Time

_____
Facility Name