UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Reach Out

Company or agency sponsoring the study: National Institutes of Health

Principal Investigator:
Mark A. Ilgen, Ph.D., Professor, University of Michigan Department of Psychiatry

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to provide your informed consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

Research studies hope to make discoveries and learn new information about certain conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies don't always offer direct benefit. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, such as amount of time required. In your decision to participate in this study, consider all of these matters carefully.

The purpose of this research study is to learn about people who use the 988 Suicide & Crisis Lifeline during a suicidal crisis and those who don't. We would also like to learn whether people who have experienced a suicidal crisis could benefit from participating in a therapy session about their thoughts and perceptions of the 988 Lifeline.

This research study is recruiting people who have completed the screening survey and reported having experienced a suicidal crisis at some time in their life. If you choose to take part, first you will be asked to complete the 60-90-minute baseline assessment. You will then be randomly placed into one of two sessions (assigned by chance in a process similar to "flipping a coin"). If you are assigned to Session 1, you will be asked to take part in a 60-minute one-on-one session with a study therapist to discuss the 988 Lifeline. If you are in Session 2, you will be asked to take part in a 15-minute review of informational materials about the 988 Lifeline. These sessions will be audio-recorded (voice only) but you do not have to agree to be recorded to be in the study. Afterwards both sessions will be asked to complete a brief survey about the session. You will then be asked to complete three follow-up assessments, at 4-, 8-, and 12-months from the time you enrolled in the study. The follow-up assessments will take about 60-75 minutes each. You can earn up to $225 and the study will last about 12 months.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include potential loss of confidentiality and discomfort when answering sensitive questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by helping us discover how to improve services for people who experience suicidal crises. More information will be provided later in this document.

You can decide not to be in this study. Participation is completely voluntary.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this research study is to learn about people who use the 988 Suicide & Crisis Lifeline during a suicidal crisis and those who don't. We would also like to learn whether people who have experienced a suicidal crisis could benefit from participating in a therapy session about their thoughts and perceptions of the 988 Lifeline.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To take part in this study you must be at least 21 years old, and have initially qualified for the study by completing the screening survey.

3.2 How many people are expected to take part in this study?

We expect about 500 people to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to take part in this study, you will be asked to complete the following:

Baseline Assessment: The baseline assessment will take about 60-90 minutes to complete. We will ask questions about topics such as suicide, drug and alcohol use, treatment and service use, and perception of those services. Part of the assessment will be done by answering questions on an online survey, paper survey, or by phone; the other part will be completed by interview questions asked by research staff in-person, via phone, or video conference call.

Because we will need to contact you for follow-up assessments, we will ask for your contact information and for the contact information of people who could be able to help us contact you. You will be eligible to receive a one-time payment of $10 for updating your contact information after (or around the time of) discharge from a treatment site.

Session: After completing the baseline assessment you will be randomly placed into one of two sessions (assigned by chance in a process similar to "flipping a coin"):

Session 1: If you are in Session 1, you will be asked to take part in a 60-minute one-on-one session with a study therapist to discuss the 988 Lifeline.

Session 2: If you are in Session 2, you will receive informational materials about the 988 Lifeline and spend about 15 minutes reviewing these materials with a member of our study team.

We will audio-record (voice only) all sessions to be sure that that the research therapists are conducting the sessions the same way for everyone. These recordings will be used only for this research study. You will be asked for your permission to be audio-recorded later in the form. You may still take part in the study if you don't want to be audio-recorded.

At the end of the session, you will be asked to answer a short survey about your session, which will take approximately 5-10 minutes.

Follow-Up Assessments: Study staff will contact you to schedule follow up assessments at about 4, 8, and 12-months after you first enrolled in the study. The 4-, 8-, and 12-month follow-ups will take about 60-75 minutes to complete. The assessments will ask similar questions as the baseline assessment and involve a survey and interview.

4.2 How much of my time will be needed to take part in this study?
Baseline and Session activities will last up to 2.5 hours for those in Session 1 and about 1.5 hours for those in Session 2. The 4-, 8-, and 12-month follow-ups will last about 60-75 minutes each. Please see chart in section 8 for more details about timing of study activities.

4.3 When will my participation in the study be over?
Your total participation in the study will last about 12 months and will be over once you've completed the 12-month follow-up survey and interview.

4.4 What will happen with my information used in this study?
Your collected information may be shared with the sponsor of this study (National Institutes of Health).

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers (meaning any information that would identify you, like name, address or phone number, would be removed) and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
Some of the questions that will be asked and the session topic are about sensitive or personal information such as experiences with suicide and suicidal thoughts, and substance use. These questions or topics may make you feel uncomfortable or anxious. You may skip any question you don't want to answer and you are free to end any session or leave the study at any time. Study therapists will conduct sessions and interviews in private areas to ensure privacy. You will be asked during sessions to try not to say your name or any information that would allow someone to determine who you are from the audio recording.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study. You may also want to tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study, however it may help you to learn about options for obtaining help when in a suicidal crisis, including receiving resources such as the numbers for the 988 Lifeline and other help organizations. Your participation may help us discover how to improve services for people who experience suicidal crises in the future.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is voluntary. Choosing not to take part in this study will not affect you in any way or the care you receive.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
We do not expect that you would experience any harm if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. By agreeing to participate, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Total compensation for taking part in the entire study is $225. You will receive study payment (i.e. a gift card) after completing each study activity listed below.

Time Period	Approximate length	Amount
Baseline Assessment	60-90 minutes	$40
*Session 1 session and survey	60 minutes	No payment
*Session 2 session and survey	15 minutes	No payment
Contact incentive (one-time payment)	5 minutes	$10
4-month follow up Assessment	60-75 minutes	$50
8-month follow up Assessment	60-75 minutes	$50
12-month follow up Assessment	60-75 minutes	$75
		Total: Up to $225

*You will only be included in one group

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

To keep your information confidential, we'll create a unique study ID number to use for your information, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who participate, no one outside our study team will be able to figure out who participated or which people gave which answers. Your name and other identifying information will be kept securely and separately from your research data. Your contact information will be stored in a secure REDCap database. REDCap is a HIPAA-compliant web application. Paper data will be stored in locked file cabinets. Audio recordings will be collected using a digital recorder and interview sessions will be encrypted and immediately uploaded to a password protected UM server and deleted from the recorder.

The online surveys you will take are designed and administered using the Qualtrics Research Suite through the University of Michigan (https://www.qualtrics.com/research-core/). Qualtrics meets the rigorous privacy standards enforced on health care records by the Health Insurance Portability and Accountability Act (HIPAA). No identifying information is directly linked to your answers. For more information, Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statement.

You will have the option to use a video chat platform of your choice (e.g., BlueJeans, Zoom, Skype for Business, etc.) to complete some of your study activities. Your confidentiality will be kept to the degree permitted by the technology being used. If a platform is used which is not affiliated with the University of Michigan (i.e., Facetime), it is possible that you could be automatically recorded by the platform – similar to when you use these platforms in everyday life. Although every reasonable effort will be taken, confidentiality during actual web-based or video chat communication procedures cannot be guaranteed.

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 them 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 also DOES NOT prevent your 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.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.2 What protected information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my information expire?

Your permission will not expire unless you cancel it.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report a problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Mark A. Ilgen, Ph.D. **Mailing Address:** 2800 Plymouth Road Ann Arbor, MI 48109 **Telephone:** (734) 845-3646 **Email:** marki@med.umich.edu	**Study Coordinator:** Amanda Price, MS **Mailing Address:** 2800 Plymouth Road Ann Arbor, MI 48109 **Telephone:** (734) 764-3662 **Email:** amhprice@med.umich.edu
Study Email: um-reachout@med.umich.edu	

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

This study involves audio recording. Even if you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____