VA INFORMED CONSENT PROCESS CHECKLIST

Complete this checklist for each consent obtained and file with the original informed consent document

RESEARCH STUDY IDENTIFICATION (Required information)
STUDY TITLE: ___ Link Up: Facilitating use of the Veterans Crisis Line in High-Risk Patients_____
PI: __Mark Ilgen, PhD_____
NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____
ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____

ORIGINAL FORM VERSION: 4/15/09. REVISIONS: 9/17/09, 10/30/09, 11/30/09, 12/07/11, 2/27/12, 10/7/13

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			| | |	/ /
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Todays Date (mm/dd/yy)**

A.	**Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been Checked and Verified Accurate and appear in the proper location**
B.	**DATE AND TIME (ICD) WAS REVIEWED AND DEEMED COMPLETE AND VALID** ****Must be prior to date/time of Subject's First Study Activity****
C.	**DATE AND TIME OF THE SUBJECT'S FIRST STUDY ACTIVITY OR INVOLVEMENT**
	Verify and Initial each requirement below.
1.	**Informed consent and HIPAA Authorization, if required by VA-IRB was obtained from this subject prior to study participation.**
2.	**A VA Scope of Practice Form has been signed by the PI and approved by the VA IRB which designates me as an authorized agent of the PI and qualified to obtain consent for this study.**
3.	**This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.**
4.	**All aspects of this subject's study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD.**
5.	**If required, a scanned image of the Research Enrollment Note, Consent Form and/or HIPAA Authorization will be entered into the subject's electronic medical record (CPRS).**
6.	*Subject has been consented using the most recently approved, VA date-stamped version of the consent form (VA Form 10-1086) and HIPAA Authorization Form (VA Form 10-0493).*
7.	**A copy of the completed and signed, original informed consent document has been issued to this subject and the subject was instructed to retain that copy for reference and to ask any and all questions that might arise throughout their study involvement.**
8.	**The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the VAAAHS IRB Coordinator. The subject has been reminded to call with any questions or concerns. Cathy Kaczmarek @ 734.845.3439**
9.	**The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.**
10.	**Original ICDs and all copies are printed and issued as single-sided documents and that the original signed ICD must be kept in the investigator's project files on VA property.**
11.	Upon completion of the Informed Consent Process, this subject's name was added to the Master List of All Subjects. [Per revised VHA Handbook 1200.05 (11/12/14) a MLS is no longer required, but a list of all enrolled participants is considered good research practice.]
12.	I know I can contact the VAAAHS IRB Coordinator at 734.845.3439 or the Research Compliance Officer at 734.845.3766 if I have questions or concerns regarding the consent of this or any individual considering study participation.

2/19/14, 4/1/14, 6/18/14, 12/19/14

Department of Veterans Affairs Research Consent Form	VA AAHS Research IRB Approved 6/09/2016

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	Mark Ilgen, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	06/09/2016	

PURPOSE OF RESEARCH STUDY:

The purpose of the study is to learn about Veterans who use the Veterans Crisis Line during a suicidal crisis and those who don't. We would also like to learn whether or not Veterans who have experienced a suicidal crisis could benefit from participating in a discussion about their thoughts and perceptions of the Veterans Crisis Line. You have been invited to participate in this research study because you are a patient in this VA psychiatry inpatient unit and were identified as having experienced a suicidal crisis (i.e. recent suicide attempt, significant suicidal thoughts). This is a joint study between the Battle Creek and Ann Arbor VA facilities.

DESCRIPTION:

This is a two part study. Part 1 involves completing a survey only. Based on some of your answers you may be eligible to participate in Part 2. Below is more detail about Part 1 and Part 2:

Part 1: We plan to enroll up to approximately 1042 patients for Part 1 – Screening of this study. If you decide to participate, we will ask you to complete a screening survey, which will take approximately 15-30 minutes. The survey asks questions about topics such as your thoughts and behaviors related to suicide, overall mental health and physical functioning, and your utilization of treatment services, such as the Veterans Crisis Line. Depending on your answers to the screening survey, you may be eligible to participate in the full study (Part 2). If you are found not eligible for participation in the full study, then your participation will be complete at the end of Part 1 and you will have no further contact with our research staff.

Part 2: We plan to enroll approximately 500 patients for Part 2 of this study. If you are eligible and decide to participate in the full study, you will be asked to complete the following:

Baseline Assessment: The baseline assessment will take approximately 45-60 minutes to complete. We will ask questions about topics such as suicide, drug and alcohol use, treatment and service utilization, and perception of those services. You will complete part of the assessment yourself by answering questions on a paper survey and the other part will include interview questions asked by research staff.

Intervention session: After completing the baseline assessment you will be randomly placed into one of two groups (assigned by chance in a process similar to "flipping a coin"):
Group 1: If you are in Group 1, you will be asked to participate in a 30-45 minute one-on-one intervention session with a member of our study team to discuss the Veterans Crisis hotline. These sessions will be audio recorded and reviewed by research staff for training purposes and to ensure that the research team is following protocol (making sure that all research team members conduct the sessions in the same way).
Group 2: If you are in Group 2, you will be asked to participate in a brief discussion with a member of our study team, and you will receive informational materials about the Veterans Crisis Line.
Afterwards both groups will be asked to answer some additional questions, which will take approximately 5-10 minutes.

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Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	Mark Ilgen, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	06/09/2016	

Follow-Up Assessments: Study staff still will contact you to schedule your follow up assessments at about 3, 6, and 12-months after study enrollment. These follow-up sessions will usually take approximately 45-60 minutes. The assessments will ask similar questions as the baseline assessment

Your total participation in Part 2 of the study (i.e. baseline survey, intervention, and 3 follow-up surveys) is expected to occur over a period of approximately 12 months. After you complete the study, we may contact you for an additional interview to ask about your study experience. If you choose to participate in the interview, you will sign a separate consent form for that part.

RISKS:

You may experience some discomfort when answering questions, such as questions regarding your experiences with suicide and suicidal thoughts. This type of discomfort is expected to be temporary. You may choose not to answer any questions that make you uncomfortable or that you do not wish to answer.

Another risk is potential loss of confidentiality of some of your personal information. We may be required to break confidentiality if we believe that there is a risk of harm to yourself or someone else (for example, you may harm yourself, someone else, or someone is harming you, or in cases of child or elder abuse). This means that we may be required to inform your regular care providers or authorities to protect you or others. The information we disclose will be relevant to your care and may have been information we obtained during the research, such as your thoughts to harm yourself, your name, and contact information,

As with any research study, there may be other risks that are unforeseeable at this time.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a 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 information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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 you disclose intent to hurt yourself, others, or if you are being hurt.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to get research information, then the researchers may not use the Certificate to withhold that information.

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	Mark Ilgen, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	06/09/2016	

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.

BENEFITS:
Your participation may help us discover how to improve services for veterans in the future. If you participate in Part 2, you may find that participating in this study helps you to learn about options you may have for obtaining help when in a suicidal crisis. However, we cannot and do not guarantee or promise that you will benefit by participating in this study.

ALTERNATE COURSES OF ACTION:
You do not have to participate in this study. You may withdraw from the study at any time without penalty. By doing so, you will not lose any benefits that you may be entitled to. If you choose not to participate in this study, your decision will not affect your eligibility to receive standard health care at the Ann Arbor VAMC.

STATEMENT OF RESEARCH RESULTS:
Research data collected as part of this study will be stored according to the privacy and security guidelines established by the VHA. Only authorized research staff will have access to your research data and research files. These authorized research staff may have access to viewing your paper forms and medical records. If you participate in Part 2, authorized research staff may also access your medical records to obtain your contact information to schedule and conduct follow-up appointments. Your name and other identifying information (consent form) will be stored separately from research data (e.g. survey and interview answers). Unique ID numbers will be substituted for names to protect your identity in the data file. Data on paper will be stored in locked filing cabinets at Ann Arbor VA research offices. All electronic study data will be kept in restricted access files and stored on the VA network server. Paper files may be stored on the secure network drive as a PDF. Because this is a joint study between the Battle Creek VAMC and Ann Arbor VAMC, electronic data may be shared/transmitted through the use of VAMC secure servers at either site.

If you participate in Part 2, the audiotapes of the sessions will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate the research staff who are leading the sessions. Audio computer files will be confidential and access will be limited to authorized research staff.

Researchers from the Battle Creek Health Care System and the Ann Arbor VA Health Care System will analyze the data collected from this study. If the results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

SPECIAL CIRCUMSTANCES:
There will not be any costs to you for any additional care that you receive as a participant in this research study. The investigators of this study may have to end your participation in this study for reasons such as if it is in your best interest; you do not follow the study plan (e.g., do not complete the survey); the investigator decides that continuation could be harmful to you; the study is canceled; other administrative reasons; or other

unanticipated circumstances. If you are withdrawn from the study, it will not affect the treatment you receive from your providers at the Ann Arbor VAMC.

COMPENSATION:
For participating in Part 1, you will receive a $10 gift card after completing the screening survey.

If you are eligible after screening, and you choose to participate in Part 2, you will receive a $25 gift card for completion of the baseline assessment and a $30 gift card for each 3, 6, and 12 month follow-up assessment completed. Therefore, your maximum compensation for this part of the study could be $115.

Department of Veterans Affairs Research Consent Form	VA AAHS Research IRB Approved 6/09/2016

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	Mark Ilgen, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	06/09/2016	

RESEARCH SUBJECT'S RIGHTS:

_____ has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study.

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. VA will provide treatment for research related injury in accordance with applicable federal regulations. The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. You may be among the veterans required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Mark Ilgen can be called at 734-845-3646 during the day and or paged after hours at 734-936-6266 (then dial page ID: 15912) or the VA psychiatrist on call can be contacted at 734-769-7100 after hours. At any time, you may call the Veterans Crisis Hotline at 1-800-273-TALK (8255), and press "1" to connect to a free, 24-hour VA hotline. The sponsor of this research study is the Veterans Administration.

You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at www.annarbor.research.va.gov

I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

x_____ Signature of Subject	x_____ (Print Name)	x_____ **Todays Date (mm/dd/yy)**
x_____ Signature of person obtaining consent (Study personnel must be approved by VA IRB)	x_____ (Print Name)	x_____ **Todays Date (mm/dd/yy)**

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
VA Ann Arbor Healthcare System
2215 Fuller Rd.
Ann Arbor, MI 48105

VA Principal Investigator (PI):	**PI Contact Information:**
Mark Ilgen, Ph.D.	Mark.Ilgen@va.gov; 734-845-3646

Study Title:

Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients

Purpose of Study:

The purpose of the study is to learn about Veterans who use the Veterans Crisis Line during a suicidal crisis and those who don't. We would also like to learn whether or not Veterans who have experienced a suicidal crisis could benefit from participating in a discussion with a member of our study team about their thoughts and perceptions of the Veterans Crisis Line. You have been invited to participate in this research study because you are a patient in this VA psychiatry inpatient unit and were identified as having experienced a suicidal crisis (i.e. recent suicide attempt, significant suicidal thoughts). Based on your responses provided during the screening survey (Part 1), you may be invited to participate in further research activities, including further surveys, interviews and a discussion with a member of our study team (Part 2). This is a joint study between the Battle Creek and Ann Arbor VA facilities.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☒ Specific information concerning:

☒ alcohol abuse ☒ drug abuse ☐ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☒ Other as described: We will only access information concerning alcohol or drug abuse for participants in Part 2.

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☒ Study Sponsor/Funding Source: Veterans Administration
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☐ Academic Affiliate (institution/name/employee/department):
A relationship with VA in the performance of this study

☐ Compliance and Safety Monitors: _____
Advises the Sponsor or PI regarding the continuing safety of this study

☐ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):

☐ A Non-Profit Corporation (name and specific purpose):

☐ Other (e.g. name of contractor and specific purpose):

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Mark Ilgen, PhD
VA Ann Arbor Healthcare System
2215 Fuller Rd.
Ann Arbor, MI 48105

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print) _____

VA INFORMED CONSENT PROCESS CHECKLIST

Complete this checklist for each consent obtained and file with the original informed consent document

RESEARCH STUDY IDENTIFICATION (Required information)
STUDY TITLE: ___ Link Up: Facilitating use of the Veterans Crisis Line in High-Risk Patients_____
PI: __E. Brooke Pope, PhD_____
NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____
ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____

ORIGINAL FORM VERSION: 4/15/09. REVISIONS: 9/17/09, 10/30/09, 11/30/09, 12/07/11, 2/27/12, 10/7/13

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			| | |	/ /
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Todays Date (mm/dd/yy)**

A.	**Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been Checked and Verified Accurate and appear in the proper location**
B.	**DATE AND TIME (ICD) WAS REVIEWED AND DEEMED COMPLETE AND VALID** ****Must be prior to date/time of Subject's First Study Activity****
C.	**DATE AND TIME OF THE SUBJECT'S FIRST STUDY ACTIVITY OR INVOLVEMENT**
	Verify and Initial each requirement below.
1.	**Informed consent and HIPAA Authorization, if required by VA-IRB was obtained from this subject prior to study participation.**
2.	**A VA Scope of Practice Form has been signed by the PI and approved by the VA IRB which designates me as an authorized agent of the PI and qualified to obtain consent for this study.**
3.	**This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.**
4.	**All aspects of this subject's study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD.**
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8.	**The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the VAAAHS IRB Coordinator. The subject has been reminded to call with any questions or concerns. Cathy Kaczmarek @ 734.845.3439**
9.	**The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.**
10.	**Original ICDs and all copies are printed and issued as single-sided documents and that the original signed ICD must be kept in the investigator's project files on VA property.**
11.	Upon completion of the Informed Consent Process, this subject's name was added to the Master List of All Subjects. [Per revised VHA Handbook 1200.05 (11/12/14) a MLS is no longer required, but a list of all enrolled participants is considered good research practice.]
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Department of Veterans Affairs Research Consent Form	VA AAHS Research IRB Approved 06/09/2016

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	E. Brooke Pope, PhD	**VAMC**: Battle Creek VA Healthcare System
Version Date:	06/09/2016	

PURPOSE OF RESEARCH STUDY:

The purpose of the study is to learn about Veterans who use the Veterans Crisis Line during a suicidal crisis and those who don't. We would also like to learn whether or not Veterans who have experienced a suicidal crisis could benefit from participating in a discussion about their thoughts and perceptions of the Veterans Crisis Line. You have been invited to participate in this research study because you are a patient in this VA psychiatry inpatient unit and were identified as having experienced a suicidal crisis (i.e. recent suicide attempt, significant suicidal thoughts). This is a joint study between the Battle Creek and Ann Arbor VA facilities.

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Part 2: We plan to enroll approximately 500 patients for Part 2 of this study. If you are eligible and decide to participate in the full study, you will be asked to complete the following:

Baseline Assessment: The baseline assessment will take approximately 45-60 minutes to complete. We will ask questions about topics such as suicide, drug and alcohol use, treatment and service utilization, and perception of those services. You will complete part of the assessment yourself by answering questions on a paper survey and the other part will include interview questions asked by research staff.

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Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Todays Date (mm/dd/yy)**

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	E. Brooke Pope, PhD	**VAMC**: Battle Creek VA Healthcare System
Version Date:	06/09/2016	

Follow-Up Assessments: Study staff still will contact you to schedule your follow up assessments at about 3, 6, and 12-months after study enrollment. These follow-up sessions will usually take approximately 45-60 minutes. The assessments will ask similar questions as the baseline assessment

Your total participation in Part 2 of the study (i.e. baseline survey, intervention, and 3 follow-up surveys) is expected to occur over a period of approximately 12 months. After you complete the study, we may contact you for an additional interview to ask about your study experience. If you choose to participate in the interview, you will sign a separate consent form for that part.

RISKS:

You may experience some discomfort when answering questions, such as questions regarding your experiences with suicide and suicidal thoughts. This type of discomfort is expected to be temporary. You may choose not to answer any questions that make you uncomfortable or that you do not wish to answer.

Another risk is potential loss of confidentiality of some of your personal information. We may be required to break confidentiality if we believe that there is a risk of harm to yourself or someone else (for example, you may harm yourself, someone else, or someone is harming you, or in cases of child or elder abuse). This means that we may be required to inform your regular care providers or authorities to protect you or others. The information we disclose will be relevant to your care and may have been information we obtained during the research, such as your thoughts to harm yourself, your name, and contact information,

As with any research study, there may be other risks that are unforeseeable at this time.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a 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 information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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 you disclose intent to hurt yourself, others, or if you are being hurt.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to get research information, then the researchers may not use the Certificate to withhold that information.

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	E. Brooke Pope, PhD	**VAMC**: Battle Creek VA Healthcare System
Version Date:	06/09/2016	

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.

BENEFITS:

Your participation may help us discover how to improve services for veterans in the future. If you participate in Part 2, you may find that participating in this study helps you to learn about options you may have for obtaining help when in a suicidal crisis. However, we cannot and do not guarantee or promise that you will benefit by participating in this study.

ALTERNATE COURSES OF ACTION:

You do not have to participate in this study. You may withdraw from the study at any time without penalty. By doing so, you will not lose any benefits that you may be entitled to. If you choose not to participate in this study, your decision will not affect your eligibility to receive standard health care at the Battle Creek VAMC.

STATEMENT OF RESEARCH RESULTS:

Research data collected as part of this study will be stored according to the privacy and security guidelines established by the VHA. Only authorized research staff will have access to your research data and research files. These authorized research staff may have access to viewing your paper forms and medical records. If you participate in Part 2, authorized research staff may also access your medical records to obtain your contact information to schedule and conduct follow-up appointments. Your name and other identifying information (consent form) will be stored separately from research data (e.g. survey and interview answers). Unique ID numbers will be substituted for names to protect your identity in the data file. Data on paper will be stored in locked filing cabinets at Ann Arbor VA research offices. All electronic study data will be kept in restricted access files and stored on the VA network server. Paper files may be stored on the secure network drive as a PDF. Because this is a joint study between the Battle Creek VAMC and Ann Arbor VAMC, electronic data may be shared/transmitted through the use of VAMC secure servers at either site.

If you participate in Part 2, the audiotapes of the sessions will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate the research staff who are leading the sessions. Audio computer files will be confidential and access will be limited to authorized research staff.

Researchers from the Battle Creek Health Care System and the Ann Arbor VA Health Care System will analyze the data collected from this study. If the results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

SPECIAL CIRCUMSTANCES:

There will not be any costs to you for any additional care that your receive as a participant in this research study. The investigators of this study may have to end your participation in this study for reasons such as if it is in your best interest; you do not follow the study plan (e.g., do not complete the survey); the investigator

decides that continuation could be harmful to you; the study is canceled; other administrative reasons; or other unanticipated circumstances. If you are withdrawn from the study, it will not affect the treatment you receive from your providers at the Battle Creek VAMC.

COMPENSATION:
For participating in Part 1, you will receive a $10 gift card after completing the screening survey.

If you are eligible after screening, and you choose to participate in Part 2, you will receive a $25 gift card for completion of the baseline assessment and a $30 gift card for each 3, 6, and 12 month follow-up assessment completed. Therefore, your maximum compensation for this part of the study could be $115.

Title of Study:	Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients	
Principal Investigator:	E. Brooke Pope, PhD	**VAMC**: Battle Creek VA Healthcare System
Version Date:	06/09/2016	

RESEARCH SUBJECT'S RIGHTS:

_____ has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study.

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. VA will provide treatment for research related injury in accordance with applicable federal regulations. The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. You may be among the veterans required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Brooke Pope can be called at 269-966-5600 extension 31634 during the day. Mark Ilgen can be called at 734-845-3646 during the day and or paged after hours at 734-936-6266 (then dial page ID: 15912) or the Battle Creek VA psychiatrist on call can be contacted at 269-966-5600 extension 33857 after hours. At any time, you may call the Veterans Crisis Hotline at 1-800-273-TALK (8255), and press "1" to connect to a free, 24-hour VA hotline. The sponsor of this research study is the Veterans Administration.

You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the Battle Creek VA and Ann Arbor VA at www.annarbor.research.va.gov.

I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

x_____	x_____	x_____
Signature of Subject	(Print Name)	**Todays Date (mm/dd/yy)**
x_____	x_____	x_____
Signature of person obtaining consent (Study personnel must be approved by VA IRB)	(Print Name)	**Todays Date (mm/dd/yy)**

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
Battle Creek VA Medical Center
5500 Armstrong Road
Battle Creek, MI 49037-7314

VA Principal Investigator (PI):	**PI Contact Information:**
E. Brooke Pope, Ph.D.	Elizabeth.Pope2@va.gov; 269-966-5600 x31634

Study Title:

Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients

Purpose of Study:

The purpose of the study is to learn about Veterans who use the Veterans Crisis Line during a suicidal crisis and those who don't. We would also like to learn whether or not Veterans who have experienced a suicidal crisis could benefit from participating in a discussion with a member of our study team about their thoughts and perceptions of the Veterans Crisis Line. You have been invited to participate in this research study because you are a patient in this VA psychiatry inpatient unit and were identified as having experienced a suicidal crisis (i.e. recent suicide attempt, significant suicidal thoughts). Based on your responses provided during the screening survey (Part 1), you may be invited to participate in further research activities, including further surveys, interviews and a discussion with a member of our study team (Part 2). This is a joint study between the Battle Creek and Ann Arbor VA facilities.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☒ Specific information concerning:

☒ alcohol abuse ☒ drug abuse ☐ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☒ Other as described: We will only access information concerning alcohol or drug abuse for participants in Part 2.

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☒ Study Sponsor/Funding Source: Veterans Administration
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☐ Academic Affiliate (institution/name/employee/department):
A relationship with VA in the performance of this study

☐ Compliance and Safety Monitors: _____
Advises the Sponsor or PI regarding the continuing safety of this study

☐ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):

☐ A Non-Profit Corporation (name and specific purpose):

☐ Other (e.g. name of contractor and specific purpose):

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

E. Brooke Pope, PhD
Battle Creek VA Medical Center
5500 Armstrong Road
Battle Creek, MI 49037-7314

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print) _____