# 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) |
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| | | | \| \| \| | / / |

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|---|---|
| **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<br>**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 734.845.4013 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, 4/27/15**

| Department of Veterans Affairs Research Consent Form | VA AAHS Research IRB Approved 2/14/2019 |
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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:** | February 14, 2019 | |

**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 like to learn more about the discussion you participated in about your thoughts and experiences related to the Veterans Crisis Line. You have been invited to participate in this research interview because you were enrolled in part 2 of the study and previously participated in the Crisis Line Facilitation discussion at the VA Ann Arbor or Battle Creek Healthcare System. This is a joint study between the Battle Creek and Ann Arbor VA facilities.

**DESCRIPTION:**
We plan to enroll approximately 10 patients for the interview portion of this study. If you decide to participate, we will ask you to complete one interview, either in person or over the phone, which will take approximately 30-45 minutes. These interviews will be audio-recorded. The interview asks questions about topics such as your thoughts about and experience of the Crisis Line Facilitation (CLF) intervention, and your ideas to make it more appealing and convenient to other Veterans.

**RISKS:**
You may experience some discomfort when answering questions related to your experience with the CLF discussion. This type of discomfort is expected to be temporary. You may refuse 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.

**RESEARCH SUBJECT IDENTIFICATION: (Required information)**

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

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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:** | February 14, 2019 | |

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.

**BENEFITS:**
Your participation may help us discover how to improve services for Veterans in the future. However, we cannot and do not guarantee or promise that you will benefit by participating in this interview.

**ALTERNATE COURSES OF ACTION:**
You do not have to participate in this interview. You may withdraw from this research 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.

Your name and other identifying information (consent form) will be stored separately from research data (e.g. 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 Battle Creek and 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.

The audiotapes of the interviews will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate responses to the interview questions about the CLF

discussion. 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 interview. 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 participating in this research interview. 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 interview); 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, you may continue to receive treatment from your providers at the Ann Arbor VAMC.

**COMPENSATION:**
You will receive $30 in gift cards after completing the interview.

| Department of Veterans Affairs Research Consent Form | | VA AAHS Research IRB Approved 2/14/2019 |
|---|---|---|
| **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:** | February 14, 2019 | |

**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.

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

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

# 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) |
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| **STUDY TITLE: _____Link Up: Facilitating use of the Veterans Crisis Line in High-Risk Patients_____**<br>**PI: _____Mark Ilgen, PhD_____**<br>**NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____**<br>**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)**

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| **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** |
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| **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).*** |
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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.** |
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| **12.** | **I know I can contact the VAAAHS IRB Coordinator at 734.845.3439 or the Research Compliance Officer at 734.845.4013 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, 4/27/15**

| Department of Veterans Affairs Research Consent Form | VA AAHS Research IRB Approved 2/14/2019 |
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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:** | February 14, 2019 | |

**PURPOSE OF RESEARCH STUDY:** The purpose of this interview is to learn about Veterans who use the Veterans Crisis Line during a suicidal crisis and those who don't. In this interview we hope to discuss the Crisis Line Facilitation (CLF) intervention that took place on the inpatient psychiatric unit. You were selected as a possible participant in this study because you work on the Ann Arbor VA or Battle Creek VA psychiatric inpatient units or are a suicide prevention coordinator at one of these locations.

**DESCRIPTION:** This research project is looking to interview approximately 8 employees who work on the psychiatric inpatient units or are suicide prevention coordinators at the VA Ann Arbor and VA Battle Creek Health Care Systems. If you choose to participate, you will be asked to complete a one-time interview about the CLF intervention that will take about 30 minutes. We will discuss the intervention and how it impacted care on the unit and with patients, as well as what changes might facilitate broader implementation and expansion to other clinical settings.

**RISKS:** This interview involves a minor risk of discomfort when discussing treatment decisions made by psychiatric inpatient staff. You may choose not to answer any question that makes you uncomfortable or that you do not wish to answer.

Another risk is potential loss of confidentiality of some of your personal information. We have taken many steps to prevent breaches of confidentiality, including storing your name and identifying information separately from study data and keeping all data in a locked cabinet and on a secure computer server in a limited access protected file.

There may be other risks that are unforeseeable at this time.

**BENEFITS:** Your participation may help us discover how to improve services for Veterans in the future. However, we cannot and do not guarantee or promise that you will benefit by participating in this interview.

**ALTERNATE COURSES OF ACTION:** You do not have to participate in this interview. You may withdraw from this research 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 employment at the VA Ann Arbor or VA Battle Creek Healthcare Systems.

**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

**RESEARCH SUBJECT IDENTIFICATION: (Required information)**

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

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 Battle Creek and 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.

The audiotapes of the interviews will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate responses to the interview questions about the CLF discussion. 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 these interviews. 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 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 research for reasons such as: it is in your best interest; you do not follow the study plan (e.g., do not complete the interview); the investigator decides that continuation could be harmful to you or others; the study is canceled; other administrative reasons; or other unanticipated circumstances.

**COMPENSATION:** You will not receive any compensation for your participation in this interview.

| **Department of Veterans Affairs Research Consent Form** | | **VA AAHS Research IRB** Approved 2/14/2019 |
|---|---|---|
| **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:** | February 14, 2019 | |

**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.

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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.

| | | |
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| x_____ Signature of Subject | x_____ (Print Name) | x_____ **Todays Date (mm/dd/yy)** |
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**IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.**

**You must use the new HIPAA Authorization Form found at this link –**

**http://www.annarbor.research.va.gov/ANNARBORRESEARCH/resappforms.asp**

**VA Form 10-0493 - Dated May 2014**

***Use of VA Form 10-3203 is no longer required. However, the consent form must include information describing any photographs, video, and/or audio recordings that will be obtained for research purposes.

# 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) |
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| **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**

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| **1.** | **Informed consent and HIPAA Authorization, if required by VA-IRB was obtained from this subject prior to study participation.** |
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| **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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| **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 734.845.4013 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, 4/27/15**

| Department of Veterans Affairs Research Consent Form | VA AAHS Research IRB Approved 2/14/2019 |
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| | | |
|---|---|---|
| **Title of Study:** | Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients | |
| **Principal Investigator:** | E. Brooke Pope, PhD | **VAMC**: VA Battle Creek Healthcare System |
| **Version Date:** | February 14, 2019 | |

**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 like to learn more about the discussion you participated in about your thoughts and experiences related to the Veterans Crisis Line. You have been invited to participate in this research interview because you were enrolled in part 2 of the study and previously participated in the Crisis Line Facilitation discussion at the VA Ann Arbor or Battle Creek Healthcare System. This is a joint study between the Battle Creek and Ann Arbor VA facilities.

**DESCRIPTION:**
We plan to enroll approximately 10 patients for the interview portion of this study. If you decide to participate, we will ask you to complete one interview, either in person or over the phone, which will take approximately 30-45 minutes. These interviews will be audio-recorded. The interview asks questions about topics such as your thoughts about and experience of the Crisis Line Facilitation (CLF) intervention, and your ideas to make it more appealing and convenient to other Veterans.

**RISKS:**
You may experience some discomfort when answering questions related to your experience with the CLF discussion. This type of discomfort is expected to be temporary. You may refuse 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.

**RESEARCH SUBJECT IDENTIFICATION: (Required information)**

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

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.

**BENEFITS:**
Your participation may help us discover how to improve services for Veterans in the future. However, we cannot and do not guarantee or promise that you will benefit by participating in this interview.

**ALTERNATE COURSES OF ACTION:**
You do not have to participate in this interview. You may withdraw from this research 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.

Your name and other identifying information (consent form) will be stored separately from research data (e.g. 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 Battle Creek and 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.

The audiotapes of the interviews will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate responses to the interview questions about the CLF

discussion. 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 interview. 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 participating in this research interview. 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 interview); 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, you may continue to receive treatment from your providers at the Ann Arbor VAMC.

**COMPENSATION:**
You will receive $30 in gift cards after completing the interview.

| | | |
|---|---|---|
| **Title of Study:** | Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients | |
| **Principal Investigator:** | E. Brooke Pope, PhD | **VAMC**: VA Battle Creek Healthcare System |
| **Version Date:** | February 14, 2019 | |

**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 at1-800-273-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_____ | 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**

# 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_____**<br>**PI: _____Mark Ilgen, PhD_____**<br>**NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____**<br>**ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____Research Associate_____** |

**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) |
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| **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**<br>****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 734.845.4013 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, 4/27/15**

| Department of Veterans Affairs Research Consent Form | | VA AAHS Research IRB Approved 2/14/2019 |
|---|---|---|
| **Title of Study:** | Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients | |
| **Principal Investigator:** | E. Brooke Pope, PhD | **VAMC**: VA Battle Creek Healthcare System |
| **Version Date:** | February 14, 2019 | |

**PURPOSE OF RESEARCH STUDY:** The purpose of this interview is to learn about Veterans who use the Veterans Crisis Line during a suicidal crisis and those who don't. In this interview we hope to discuss the Crisis Line Facilitation (CLF) intervention that took place on the inpatient psychiatric unit. You were selected as a possible participant in this study because you work on the Ann Arbor VA or Battle Creek VA psychiatric inpatient units or are a suicide prevention coordinator at one of these locations.

**DESCRIPTION:** This research project is looking to interview approximately 8 employees who work on the psychiatric inpatient units or are suicide prevention coordinators at the VA Ann Arbor and VA Battle Creek Health Care Systems. If you choose to participate, you will be asked to complete a one-time interview about the CLF intervention that will take about 30 minutes. We will discuss the intervention and how it impacted care on the unit and with patients, as well as what changes might facilitate broader implementation and expansion to other clinical settings.

**RISKS:** This interview involves a minor risk of discomfort when discussing treatment decisions made by psychiatric inpatient staff. You may choose not to answer any question that makes you uncomfortable or that you do not wish to answer.

Another risk is potential loss of confidentiality of some of your personal information. We have taken many steps to prevent breaches of confidentiality, including storing your name and identifying information separately from study data and keeping all data in a locked cabinet and on a secure computer server in a limited access protected file.

There may be other risks that are unforeseeable at this time.

**BENEFITS:** Your participation may help us discover how to improve services for Veterans in the future. However, we cannot and do not guarantee or promise that you will benefit by participating in this interview.

**ALTERNATE COURSES OF ACTION:** You do not have to participate in this interview. You may withdraw from this research 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 employment at the VA Ann Arbor or VA Battle Creek Healthcare Systems.

**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

**RESEARCH SUBJECT IDENTIFICATION: (Required information)**

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

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.

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 Battle Creek and 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.

The audiotapes of the interviews will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate responses to the interview questions about the CLF discussion. 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 these interviews. 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 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 research for reasons such as: it is in your best interest; you do not follow the study plan (e.g., do not complete the interview); the investigator decides that continuation could be harmful to you or others; the study is canceled; other administrative reasons; or other unanticipated circumstances.

**COMPENSATION:** You will not receive any compensation for your participation in this interview.

| Department of Veterans Affairs Research Consent Form | VA AAHS Research IRB Approved 2/14/2019 |
|---|---|

| | | |
|---|---|---|
| **Title of Study:** | Link Up: Facilitating Use of the Veterans Crisis Line in High-Risk Patients | |
| **Principal Investigator:** | E. Brooke Pope, PhD | **VAMC**: VA Battle Creek Healthcare System |
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_____ 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 at1-800-273-TALK (8255), and press "1" to connect to a free, 24-hour VA hotline. The sponsor of this research study is the Veterans administration.

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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)** |

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