Official Title: Primary Care Intervention to Reduce Prescription Opioid Overdoses (POST)
ClinicalTrials.gov Number: NCT02464410
Date of ICD approval: 08/10/2017

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: __ Prescription Opioid Safety Trial (POST) **PI: _Amy Bohnert PhD_____** **NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____** **ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _Research Assistant**

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).*
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 is 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.
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

Department of Veterans Affairs Research Consent Form	VA AAHS Research IRB Approved 8/10/17

Title of Study:	Prescription Opioid Safety Trial (POST)	
Principal Investigator:	Amy Bohnert, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	August 10, 2017	

PURPOSE OF RESEARCH STUDY:
The purpose of this study is to see if a brief intervention may help improve opioid safety in individuals who use these medications (including Vicodin, Oxycontin, Percocet, morphine, codeine, Dilaudid, among others). You are being invited to participate in this study because you have been prescribed one of these medications at the Ann Arbor Veterans Affairs Medical Center (VAMC).

DESCRIPTION:
We plan to enroll a total of 450 patients for the study from VA Ann Arbor Healthcare System. If you choose to participate, you will be asked to complete the following:

Enrollment (baseline) survey: The baseline survey will take up to 45 minutes to complete and will occur usually in-person at the Ann Arbor VAMC. We will ask questions about topics such as your use of drugs and alcohol, physical and mental health, and thoughts and actions related to suicide and other moods, and use of treatment/services. Additionally, we will request a voluntary urine sample for a drug screen.

Intervention session:
After completing the baseline survey, you will be asked to participate in a 30 minute individual session with a trained research therapist, followed by a short post-test survey. You will be randomly placed into one of two groups (assigned by chance in a process similar to "flipping a coin"): 1) a motivational intervention which is designed to provide you with beneficial strategies for reducing overdose risk and coping with pain, or 2) an educational intervention designed to provide you with detailed information about pain conditions, treatments and opioid use. We are interested in learning the effects of both of these therapy groups.
These sessions will be audio taped and reviewed by research staff for training purposes and to ensure that study therapists are following protocol.

Follow-Up surveys: Study staff still will contact you to schedule your follow up interviews. Follow-up interviews will occur at about 3, 6, and 12-months after study enrollment. These follow-up sessions will usually occur in person at the Ann Arbor VAMC, and be up to 45 minutes long. The surveys will ask the same questions as the baseline survey. We will again request a voluntary urine sample for a drug screen at each visit.

Your total participation (i.e. baseline survey, intervention, and 3 follow-up surveys) is expected to occur over a period of approximately 12 months. Please note, we may enter a progress report in your medical record indicating that you are enrolled in a research study, as well as any information that may affect the medical care you receiving. The results of the urine drug screens and survey data will be kept completely confidential and will not be entered into your VA medical record or shared with any of the treatment staff at the VA. Only our study staff will have access to the results of these urine drug screens. If you are unavailable to participate in-person, we can accommodate your schedule by completing this informed consent document and voluntary urine screen in-person then complete the baseline survey, intervention session, and post-test survey over the phone.

RESEARCH SUBJECT IDENTIFICATION: (Required information)

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

Title of Study:	Prescription Opioid Safety Trial (POST)	
Principal Investigator:	Amy Bohnert, PhD	**VAMC**: VA Ann Arbor Healthcare System
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We also may try utilizing information from your medical record to reach you. If our call reaches an answering machine or someone else answers the phone, we will not mention the specifics of the study (i.e., identify you as being in the study or what the study is about); however, we may say we are calling from the VAMC.

RISKS:
You may experience some discomfort when answering sensitive questions, such as when answering questions regarding substance use and certain emotions (for example, depression). This type of discomfort is expected to be temporary. You may also find that the research surveys take a long time (about 1 hour each) and you may become tired during the assessment. You may choose not to answer any question that makes you uncomfortable or that you do not wish to answer. You may also take breaks during study assessments.

Another risk is potential loss of confidentiality of some of your personal information, for example, information on drug use and your mental health status. We have taken many steps to prevent breaches of confidentiality, including storing participant names separately from study data and keeping all data in a locked cabinet and on a secure computer server in a limited access protected file. We may be required to breach confidentiality if we believe that there is a risk of harm to yourself or someone else (ex. you harming yourself or someone else or someone else is harming you, or in cases of elder and/or child abuse) and we may be required to inform your regular care providers or other authorities to protect you or others.

We may need to use semi-private space (e.g., waiting room) when going over the informed consent and administering the surveys. We will protect your privacy and confidentiality by using lower voices and moving away from other people.

As with any research project, there may be 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 (NIH; #CC-DA-15-168). 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, if you are being hurt, or in cases of elder and/or child abuse.

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 receive research information, then the researchers may not use the Certificate to withhold that information.

Title of Study:	Prescription Opioid Safety Trial (POST)	
Principal Investigator:	Amy Bohnert, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	August 10, 2017	

BENEFITS:
Your participation in this study may help us to improve services for veterans in the future. You may find that participating in this study leads to better outcomes (i.e., lesser overdose risk from opioid medication). 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. **The surveys will be completed on paper forms**. Data on paper will be in locked filing cabinets. All electronic study data will be kept in restricted access files and stored on the VA network server. All the information you give us will be kept confidential.

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, including your contact information to schedule and conduct follow-up appointments. Your name and other identifying health information will be stored separately from research data. Unique ID numbers will be substituted for names for identification purposes to protect your confidentiality in the data file. The audiotapes of the sessions will be converted into computer files and stored on secure servers. Audio-records will be used to evaluate the therapists who are leading the sessions.

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: it is in your best interest; you do not follow the study plan (e.g., do not participate in the follow-up assessment); the investigator decides that continuation could be harmful to you or others; the study is canceled; other administrative reasons; or other unanticipated circumstances. If you are withdrawn from the study, you may continue to participate in the treatment group that you are assigned to and receive treatment from your providers at the Ann Arbor VAMC.

COMPENSATION:
You will receive $30 gift card after the completion of each assessment (i.e. initial assessment; 3, 6, and 12-month follow-up assessment), and an additional $5 at each assessment (i.e. initial assessment; 3, 6, and 12 month follow-up assessment) if you choose to provide a voluntary urine sample. To assist with travel expenses, you will receive a $10 gift card at each assessment (i.e. initial assessment; 3, 6, and 12-month

follow-up assessment). Therefore, if you complete all four assessments and provide a urine sample, your total compensation will be $180. You will only be paid for the assessments that you complete.

Title of Study:	Prescription Opioid Safety Trial (POST)	
Principal Investigator:	Amy Bohnert, PhD	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	August 10, 2017	

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. 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: Amy Bohnert can be called at 734-845-3638. After hours, Mark Ilgen, PhD can be paged at 734-936-6266 (then type in 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), option "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

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:**
Amy Bohnert, PhD	Amy.Bohnert@va.gov; 734-845-3638

Study Title:

Prescription Opioid Safety Trial (POST)

Purpose of Study:

The purpose of this study is to see if a brief intervention may help improve opioid safety in individuals who use those medications (including Vicodin, Oxycontin, Percocet, morphine, codeine, Dilaudid, among others). You are being invited to participate in this study because you have been prescribed one of these medications at the Ann Arbor Veterans Affairs Medical Center (VAMC).

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:

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 Affairs
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:

Amy Bohnert, PhD
Center for Clinical Management Research
2215 Fuller Road (152)
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) _____