PAtient-centered mUltidiSciplinary care for vEterans undergoing surgery (PAUSE): a hybrid 1 clinical effectiveness-implementation intervention trial

NCT05037292

March 23, 2021

Request for Waiver of Documentation of Informed Consent

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form must be included with all project applications when requesting a waiver of documentation of informed consent. This type of waiver can be requested when using telephone, surveys, questionnaires, or when signing the informed consent form could have a negative consequence for the participant.

I. Project Identification

Title of Project	PAtient-centered mUltidiSciplinary care for vEterans undergoing surgery (PAUSE): a hybrid 1 clinical effectiveness-implementation intervention trial
Principal Investigator	*Dr. Shipra Arya*

II. Criteria to Submit Request for Waiver of Documentation of Informed Consent

The principal investigator must check that the proposed research meets one of the following criteria in order to request a waiver of documentation of informed consent.:

☒ The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

or

☐ The only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant's wishes will govern.
NOTE: This criterion cannot be used for FDA-regulated studies.

or

☐ **For research that is subject to the 2018 Requirements,** the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
NOTE: This criterion cannot be used for FDA-regulated studies.

III. Portion(s) of Research for which Investigator is Requesting Waiver

The principal investigator must check one of the boxes below. If the second box is checked, the investigator must identify the portion(s) of the study for which the requested waiver applies: (telephone survey, mailed questionnaire, etc.)

a. Indicate which interactions with subjects for which you are applying for the waiver:

☒ This waiver request applies to all interactions with subjects detailed in the study.

☐ This waiver request applies only to the following interaction(s) with subjects:

IV. Justification for Waiver

The principal investigator must provide justification that the portion(s) of the study for which waiver is requested meets waiver criteria as selected in Section II above. A separate justification must be provided below for each intervention for which a waiver is being requested.

We are requesting a waiver of documentation of informed consent for VA Provider participation in PAUSE Board meetings, interviews and focus groups to evaluate the PAUSE intervention. Access to provider names, phone numbers and emails are requested for communication purposes, only.

All questions asked during the Service/Section Chief interviews are regarding the PAUSE intervention. No questions pertain to participant (i.e. provider) personal health information.

All questions asked during the referral interviews with high- and low-referring surgical team members are regarding the PAUSE intervention. No questions pertain to participant (i.e. provider) personal health information.

All questions asked during the focus group with PAUSE Board members are regarding the PAUSE intervention. No questions pertain to participant (i.e. provider) personal health information.

With permission form members, PAUSE Board meetings will be recorded to assist in creating PAUSE Board recommendations in patient's CPRS records. Participant (i.e. provider) personal health information will not be discussed.

V. Investigator Certification

By signature below, the principal investigator acknowledges the following:

1. This project involves no more than minimal risk to the participant. *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (VHA Directive 1200.05)*

2. Even if the requested waiver is granted, the VA Central IRB may require other conditions, such as providing the participants with an information sheet about the research.

2. If the second box in Section II is checked, each participant must be asked whether they want documentation linking them with the research, and the participant's wishes will govern.

3. Even though the requested waivers may be granted, I acknowledge that it is still my responsibility to ensure that there is an appropriate informed consent process and that the rights and welfare of the participants are protected in accordance with VA and other federal requirements.

Signature

3/1/2021

Date

Section VI is for VA Central IRB use only.

IV. Review by VA Central IRB

This section is to be completed by the VA Central IRB Co-Chair based upon the actions taken at a convened meeting of the VA Central IRB or during the expedited review process.

This request has been reviewed in accordance with VA requirements for the waiver of documentation of informed consent and the following determination has been made:
(Check one only)

x	The request for waiver or documentation of informed consent requirement is approved for this study as requested.
☐	The request for waiver of the documentation of informed consent is approved only as indicated in the below remarks.
☐	The request for waiver of documentation of informed consent is not approved. The reasons for the disapproval are indicated in the remarks below.

Remarks:

Fred Hendler
174015

Digitally signed by Fred Hendler 174015
Date: 2021.03.23 15:00:27 -04'00'

Signature of VA Central IRB Co-Chair

Date: _____