Understanding Perceived Access and Receipt of Gender-affirming Treatments Among Transgender Veterans

NCT06615401

April 7, 2023

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	Understanding perceived access and receipt of gender-affirming treatments among transgender Veterans
Principal Investigator	Guneet K. Jasuja

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:

Survey Aim 2 and Qualitative Aim 3. For Database Aim 1, as per standard practice, we are requesting a waiver of informed consent since this is a database study and sample will be recruited from the VA administrative data.

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.

The study presents no more than minimal risk of harm to participants. The study team will not identify, directly or indirectly, any individual participant in any report of this research and will not disclose any participant identifiers in any manner. All information will be securely stored in locked files or behind the VA firewall on a network folder for this project. Participants for both the survey aim 2 and qualitative aim 3 will be recruited across multiple sites, and while this waiver does not remove the requirement for consent, it will allow participants to enroll in the study without having to return a document via mail. It will also allow the study team to complete the research activities for these two aims within the allotted timeframe.

All participants for the survey aim 2 and qualitative aim 3 will be given written information so that they can see and read all the elements of informed consent for this study. For the survey aim 2, for participants who are interested in completing the electronic survey will be guided through the online consent process and sign electronic informed consent by checking a box indicating their consent before starting the electronic survey. For participants who wish to complete a mailed survey, filling out the survey and choosing to mail it back is indication of their willingness to participate in the study.For participants who wish to complete the survey over phone and for qualitative aim 3, research team members will review the content of the informed consent document over the phone with the participant and provide ample time for asking questions, until all questions have been answered. The participant will then be asked if they agree to the conditions of the consent form (i.e., they consent). A yes' answer will be noted in the study logs. Verbal consent will be obtained again prior to the start of the survey or the interview. Participants will be reminded that their participation is voluntary, and they may choose to leave the focus group at any time. They will also be reminded that participation in the survey or the interview or information shared will not impact their medical care in any way.

V. Investigator Statement

As Principal Investigator I acknowledge 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.

3. 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.

4. 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.

VI. Review by VA Central IRB

This section is to be completed by the designated VA Central IRB Member based upon their expedited review of the project or actions taken at a convened meeting of the VA Central IRB.

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:

FREDDY HENDLER Digitally signed by FREDDY HENDLER Date: 2023.04.07 14:00:42 -04'00'

Signature of VA Central IRB Member

Date: _____