Health Information for Infected Veterans

NCT03190317

May 16, 2019

Participants Name: _____ **Date:** _____

Social Security Number:_____ **VAMC: Bedford, MA**

Principal Investigator: Keith McInnes, ScD

IRB FORM 04a 09-02-16

Title of Study: Health Information for Infected Veterans (HI-FIV)

Sponsor of the Study: VA/HSR&D

1. Purpose of study and how long it will last: You are invited to participate in a research study of My Health*e*Vet (MHV) use by Veterans diagnosed with Human Immunodeficiency Virus (HIV) and VA providers/staff who care for them. We hope to learn the value that providers/staff perceive in MHV tools for themselves and for patients, whether they encourage (or discourage) patient use of MHV, how MHV fits into clinical workflow, the role of secure messaging triage teams, and barriers they perceive as preventing their patients from using MHV for chronic disease management tasks. You were selected as a possible subject in this study because you are a VA provider/staff who cares for HIV patients and have either used or not used MHV. Your involvement will be to participate in an interview that will last about 30 minutes.

2. Description of the study including procedures to be used: If you choose to participate, a research team member will contact you to participate in a one-time audio-recorded interview over the telephone for approximately 30 minutes. The purpose of the interview is to figure out why certain patients and providers/staff use MHV the way they do, understand any technical MHV issues, and learn about attitudes and perceptions that may prevent others from using MHV. The research team member may ask you questions about attitudes about patients communicating electronically with providers, and patients having access to parts of their medical record, such as clinician notes and lab results.

Since this interview will be audio-recorded, so the researchers can review and summarize your responses, you will be asked to provide verbal consent to give us permission to voice record you as part of the research. If you do not wish to be audio-recorded, but want to participate in the study, the research team member will take notes instead. The recordings will be used only for this study. Audio recordings will be transcribed, meaning someone will listen to the recording and write down your words. The recordings will be transcribed by a VA-approved or in-house transcription service. Steps will be taken to ensure that recordings and transcripts remain confidential. They will be transferred to the transcription service securely in accordance with VA policy. Disclosure to a VA-approved transcription service would be the only disclosure outside the VA. You can choose to participate in the interview but not be audio recorded, or you can have us stop recording at any time. We plan to interview up to 24 providers/staff, up to 6 of those being at your VA.

3. Description of any procedures that may result in discomfort or inconvenience: The only foreseeable inconvenience of participating in study interviews is the time and effort you put into arranging and completing the interview. There will be no costs to you to participate in this study.

4. Expected risks of study: The risk of taking part in this study is small. It is possible that your supervisor may know you are participating in an interview but the research team will not inform your supervisor directly if you have chosen to participate or not participate in this study. Your answers will be

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kept confidential, but there is a small risk that people outside of the research team could learn the information. We make all efforts to ensure that your privacy will be protected. We will work hard to keep all your information confidential.

Confidentiality of Information: Participation in research may involve a loss of privacy. We will do our best to keep your research records confidential. All information, including notes, transcripts and interview recordings will be labeled with a code number. The code number will not be based on any information that could be used to identify you, like your social security number, initials, or birth date. We will keep the master list linking names to code numbers separately from the research data and it will be password protected. Your consent form will not be linked to the code and will be kept separately from the information. All research information will be kept in locked files at all times. Any electronic record will be kept on a secure VA computer server. Your identity will not be revealed in any reports or publications resulting from this study. All data will be retained in accordance with the VA record control schedule.

All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.

If you first agree to participate and then you change your mind, you are free to withdraw your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled.

5. Expected direct benefits of study: You will receive no direct benefit from participating in this study. The information we learn from this study will help us better understand how to communicate with and provide care for Veterans with HIV. We hope this knowledge will contribute to improving care for Veterans with HIV.

6. Alternative treatment available: Your participation in this study is completely voluntary. This is not a treatment study. You can receive treatment without participating in this study. The alternative to participating is to choose not to participate. If you decide to participate, you can change your mind at any time or refuse to answer any questions. Whether you choose to participate or not, you are at no risk of losing any benefits and the decision to participate or not will no impact your employment now or in the future. If you choose to withdraw from the study at any time your employment will not be affected. If you choose not to complete the interview, we will immediately stop collecting information from you and will withdraw you from the study. Any data already collected prior to stopping participation will still be used.

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7. Use of research results/Confidentiality: If you participate in this study, we will be extremely careful to maintain your confidentiality. The information we collect from you will be coded with an identification number that is not linked to any personal information about you and will be stored on a secure VA server behind a VA firewall. The list of participants and identification numbers will be stored on a secure VA server, separately from the data and will be password protected, with the password known only to the members of the Bedford VA study team. Your completed Informed Consent Form will be kept in a locked filing cabinet. After the information from the interview is entered into the computer, the forms with the information on them will also be kept in a locked filing cabinet. All data will be retained in accordance with the VA record control schedule.

When we write about the results of this study, no identifiable information will be linked to you or any other study participant. We will not reveal your responses to questions to your employer. If 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.

Only authorized persons will have access to the information gathered in this study which includes members of the Bedford VA study team. Study team members at the Palo Alto VA will only have access to summaries of the data and not your personal information. All data will be retained in accordance with the VA record control schedule. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.

8. Special Circumstances: If you decided to stop participating in the study we will retain whatever data we have already collected up to that point. Additionally, if you would like a copy of the study's final report please let a member of the research team know so that we can send it to you when it is ready.

Audio Recording:

I consent to having my interview audio recorded:

Yes ☐ No ☐

Participants Name: _____ **Date:** _____

Social Security Number:_____ **VAMC: Bedford, MA**

Principal Investigator: Keith McInnes, ScD

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Sponsor of the Study: VA/HSR&D

RESEARCH PARTICIPANTS' RIGHTS: I have read, or have had read to me all of the above. Dr. Keith McInnes or a member of his research team has explained the study to me and answered all of my questions. I have been told of the risks or discomfort and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of benefits to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

A research participant does not have to pay for care received as a participant in a VA research project except in accordance with federal law. Certain participants may have to pay co-payments for medical care and services provided by VA. In case there are medical problems or questions, I have been told I can call: **Shawn Dunlap, Research Coordinator at 781-687-3541, during the day and after hours I should call 781-687-2000 and ask for the doctor on-call. VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures. If I have any questions, concerns, or complaints regarding my rights as a research subject I may call Joseph Squicciarini at 781-687-2926. No money has been set aside for compensation in case of injury as a result of participating in this study however I understand that I would still have the right to file any legal action.**

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

_____	_____	
Print Name of Participant	**Date**	
_____	_____	_____
Signature of Participant's Representative* ***Only required if subject not competent.**	**Participant's Representative (print)**	**Date**
_____	_____	_____
Signature of Investigator	**Signature of the person obtaining consent**	**Date**

Participants Name: _____ **Date:** _____

Social Security Number: _____ **VAMC: Bedford, MA**

Principal Investigator: Keith McInnes, ScD

IRB FORM 04a 09-02-16

Title of Study: Health Information for Infected Veterans (HI-FIV)

Sponsor of the Study: VA/HSR&D

1. Purpose of study and how long it will last: You are invited to participate in a research study of My Health*e*Vet (MHV) use by Veterans diagnosed with Human Immunodeficiency Virus (HIV) and VA providers/staff who care for them. We hope to learn and understand how MHV can improve the self-management of chronic conditions like HIV. You were selected as a possible subject in this study because you have a diagnosis of HIV and are registered on MHV. Your involvement will be to participate in an interview that will last about 60 minutes.

2. Description of the study including procedures to be used: If you choose to participate, a research team member will contact you to participate in a one-time audio-recorded interview over the telephone for approximately 60 minutes. The purpose of the interview is to figure out why certain patients and providers/staff use MHV the way they do, understand any technical MHV issues, and learn about attitudes and perceptions that may prevent others from using MHV. The research team member may ask you questions about HIV self-management, including appointment attendance, preventive health care, management of other common illnesses and diseases co-occurring with HIV, refilling medications, medication adherence, etc.

Since this interview will be audio-recorded, so the researchers can review and summarize your responses, you will be asked to provide verbal consent to give us permission to voice record you as part of the research. If you do not wish to be audio-recorded, but want to participate in the study, the research team member will take notes instead. The recordings will be used only for this study. Audio recordings will be transcribed, meaning someone will listen to the recording and write down your words. The recordings will be transcribed by a VA-approved or in-house transcription service. Steps will be taken to ensure that recordings and transcripts remain confidential. They will be transferred to the transcription service securely in accordance with VA policy. Disclosure to a VA-approved transcription service would be the only disclosure outside the VA. You can choose to participate in the interview but not be audio recorded, or you can have us stop recording at any time. We plan to interview up to 72 Veterans, up to 12 of those being at your VA.

We will also look at your medical record. We will get information about your health and healthcare. This will include information about your physical and mental health and the care and treatment you receive.

3. Description of any procedures that may result in discomfort or inconvenience: Some of the questions in the interview will ask you about HIV self-management, including appointment attendance, preventive health care, management of other common illnesses which co-occur with HIV, refilling medications, medication adherence, etc. These may have the potential to cause you distress, although we do not anticipate this. Your answers will be kept confidential, but there is a small risk that people outside of the research team could learn the information. There will be no costs to you to participate in this study.

Participants Name: _____ **Date:** _____

Social Security Number: _____ **VAMC: Bedford, MA**

Principal Investigator: Keith McInnes, ScD

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4. Expected risks of study: The risk of taking part in this study is small. We do not expect there to be any legal risks from participating in this study. You may become upset discussing health conditions and your health care experiences. You may choose to skip any questionnaire or interview question or stop participation at any time. You may become self-conscious while being observed. We understand that individuals with HIV have experienced stigma (negative social consequences because of the diagnosis). It is possible that you may be concerned about this when participating in a study focused on HIV care. We make all efforts to ensure that your privacy will be protected. We will work hard to keep all your information confidential.

Confidentiality of Information: Participation in research may involve a loss of privacy. We will do our best to keep your research records confidential. All information, including notes, transcripts and interview recordings will be labeled with a code number. The code number will not be based on any information that could be used to identify you, like your social security number, initials, or birth date. We will keep the master list linking names to code numbers separately from the research data and it will be password protected. Your consent form will not be linked to the code and will be kept separately from the information. All research information will be kept in locked files at all times. Any electronic record will be kept on a secure VA computer server. Your identity will not be revealed in any reports or publications resulting from this study. All data will be retained in accordance with the VA record control schedule.

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You may withdraw from the study at any time. If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Shawn Dunlap, project manager, at 781-687-3541. The investigators may also withdraw you at any time from the study for one or more of the following reasons: failure to follow instructions from study staff, investigators decide that continuing your participation could be harmful for you, the study is cancelled, other administrative reasons, or if there are unanticipated circumstances.

5. Expected direct benefits of study: You will receive no direct benefit from participating in this study. The information we learn from this study will help us better understand how to communicate with and provide care for Veterans with HIV. We hope this knowledge will contribute to improving care for Veterans with HIV.

6. Alternative treatment available: Your participation in this study is completely voluntary. This is not a treatment study. You can receive treatment without participating in this study. The alternative to

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Social Security Number: _____ **VAMC:** **Bedford, MA**

Principal Investigator: Keith McInnes, ScD

Title of Study: **Health Information for Infected Veterans (HI-FIV)**

Sponsor of the Study: VA/HSR&D

participating is to choose not to participate. If you decide to participate, you can change your mind at any time or refuse to answer any questions. You will not lose any benefits if you choose not to participate. Your choice to participate or not will not impact your care. Your care will not be affected if you choose to withdraw from the study at any time. Any data already collected prior to stopping participation will still be used.

7. Use of research results/Confidentiality: We will be extremely careful to maintain your confidentiality. Your providers also will not be told whether you participated or about how patients responded to any questions. You will not be identified in any of the reports from this study. If 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. We will not use your name or recording in any presentation without your specific consent. We will not use any identifiable information linked to you or any other study participant. All data will be retained in accordance with the VA record control schedule.

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8. Special Circumstances: We will give you a $25 gift card for your participation in the study interview. If a research team member feels our interview questions are making you feel uncomfortable your participation in the study may be ended, at the decision of the research team member. Additionally, if you decided to stop participating in the study we will retain whatever data we have already collected up to that point, and you will receive the full gift card amount mentioned above. Additionally, if you would like a copy of the study's final report please let a member of the research team know so that we can send it to you when it is ready.

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Audio Recording:

I consent to having my interview audio recorded:

Yes ☐ No ☐

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I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of benefits to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

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I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done.

_____	_____	
Print Name of Participant	**Date**	
_____	_____	_____
Signature of Participant's Representative* ***Only required if subject not competent.**	**Participant's Representative (print)**	**Date**
_____	_____	_____
Signature of Investigator	**Signature of the person obtaining consent**	**Date**

IRB APPROVAL
10/10/19
EXPIRES
5/31/20 DC

Participants Name: _____ **Date:** _____

Social Security Number:_____ **VAMC: Bedford, MA**

Principal Investigator: Keith McInnes, ScD IRB FORM 04a 09-02-16

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Sponsor of the Study: VA/HSR&D

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We will also look at your medical record. We will get information about your health and healthcare. This will include information about your physical and mental health and the care and treatment you receive.

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Participants Name: _____ **Date:** _____

Social Security Number:_____ **VAMC: Bedford, MA**

Principal Investigator: Keith McInnes, ScD

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4. Expected risks of study: The risk of taking part in this study is small. We do not expect there to be any legal risks from participating in this study. You may become upset discussing health conditions and your health care experiences. You may choose to skip any questionnaire or interview question or stop participation at any time. You may become self-conscious while being observed. We understand that individuals with HIV have experienced stigma (negative social consequences because of the diagnosis). It is possible that you may be concerned about this when participating in a study focused on HIV care. We make all efforts to ensure that your privacy will be protected. We will work hard to keep all your information confidential.

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Audio Recording:

I consent to having my interview audio recorded:

Yes ☐ No ☐

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I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of benefits to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

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I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done.

_____ _____ _____

Department of Veterans Affairs

RESEARCH CONSENT FORM

Title of Study: Health Information for Infected Veterans (HI-FIV)	
Title of Consent (if different from Study Title): Consent for Provider/Staff Interview	
Principal Investigator: **Amanda Midboe, PhD**	VAMC: VA Palo Alto HCS

What is this research about?

You are invited to participate in a research study of My HealtheVet (MHV) use by Veterans diagnosed with Human Immunodeficiency Virus (HIV) and VA providers/staff who care for them. We hope to learn the value that providers/staff perceive in MHV tools for themselves and for patients, whether they encourage (or discourage) patient use of MHV, how MHV fits into clinical workflow, the role of secure messaging triage teams, and barriers they perceive as preventing their patients from using MHV for chronic disease management tasks. You were selected as a possible subject in this study because you are a VA provider/staff who cares for HIV patients and have either used or not used MHV.
This research study is looking for 60 Veterans with HIV and 30 VA providers/staff in the United States. The VA Palo Alto expects to enroll a total of 90 research study subjects.

What is expected of me? What are the study procedures?

If you choose to participate, a research team member will contact you to participate in a one-time audio-recorded interview over the telephone or in-person for about 20-30 minutes, depending on how much you have to share. The purpose of the interview is to figure out why certain patients and providers/staff use MHV the way they do, understand any technical MHV issues, and learn about attitudes and perceptions that may prevent others from using MHV. The research team member may ask you questions about attitudes about patients communicating electronically with providers, and patients having access to parts of their medical record, such as clinician notes and lab results.

Since this interview will be audio-recorded, so the researchers can review and summarize your responses, you will be asked to provide verbal consent to give us permission to voice record you as part of the research. If you do not wish to be audio-recorded, but want to participate in the study, the research team member will take notes instead.

What are the possible risks or discomforts?

This study involves the following risks, discomforts, and possible inconveniences:

The risk of taking part in this study is small. Some of the questions in the interview will ask you about HIV self-management, including appointment attendance, preventive health care, management of other common comorbidities, refilling medications, medication adherence, etc. These may have the potential to cause you distress, although we do not anticipate this. Your answers will be kept confidential, but there is a small risk that people outside of the research team could learn the information.

We will audiotape the interview and take notes. The audiotapes will be transcribed. The audiotapes, interview notes, and audiotape transcriptions will be kept in a locked file cabinet in a locked room in the office of one of the research team members. Electronic files will be kept on the password-protected VA computer system behind the VA firewall. All files will be labeled using codes rather than individual names or personal identification numbers to protect your identity. The key to the codes will only be available to selected research staff.

Will I benefit from the study?

There may not be any direct benefits to you for participating in this study.

What are my alternatives to being in this study?

The alternative to this study is not to participate.

Will I get paid?

You will not be compensated for your participation in this study.

Will I have to pay anything?

You will not have to pay anything to be in this study.

Do I have to be in this study?

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

Can I change my mind later and stop being in this study?

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled.

If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling the principal investigator, **Amanda Midboe, PhD at: 650-614-9997, dial extension 27829**.

The investigators may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff.

- The investigators decide that continuing your participation can be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you decided to withdraw your study, any data already collected prior to stopping participation will only be used with your consent.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Will my information be protected from the public?

Since this study is a collaboration between the Bedford VA and Palo Alto VA study team, members of both study team will have access to information which may identify you.

As previously mentioned, we will audiotape the interview if you give us permission and take notes during the interview. The audiotapes will be transcribed as well by a VA transcriptionist. The audiotapes, interview notes, and audiotape transcriptions will be kept in a locked file cabinet in a locked room in the office of one of the study staff. Electronic files will be kept on the password-protected VA computer system behind the VA firewall. All files will be labeled using codes rather than individual names or personal identification numbers to protect your identity. The key to the codes will only be available to selected study staff.

We will keep your name and all the information about you used in this study as confidential as possible. We may publish the results of this study for others to read, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information if they decided to audit us.

What happens if I think I've been hurt by being in this study?

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability

for negligence. For further information, you may call the Human Protections Administrator at (650) 493-5000, ext. 67593 or the V.A. Regional Counsel at (415) 750-2288.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, Amanda Midboe, PhD at: 650-614-9997, dial extension 27829. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Hannah Cheng at 650-614-9997, dial extension 27556.

What are my rights if I take part in this study?

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decided to withdraw your study, any data already collected prior to stopping participation will only be used with your consent.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;

- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

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Department of Veterans Affairs

RESEARCH CONSENT FORM

Title of Study: Health Information for Infected Veterans (HI-FIV)	
Title of Consent (if different from Study Title): Consent for Provider/Staff Interview	
Principal Investigator: **Amanda Midboe, PhD**	VAMC: VA Palo Alto HCS

STUDY INFORMED CONSENT

Do you give your verbal consent to allow the individuals and entities mentioned to obtain, use and share your health information for this research study? ___Yes ___No

Do you give your verbal consent to be audiotaped during this study? __Yes__No

Providing your verbal consent means you agree to be in this study.

_____ _____
Print Name of Participant *Date & Time*

_____ _____
Signature of Person Obtaining Consent *Date & Time*

_____
Name of Person Obtaining Consent

Department of Veterans Affairs

RESEARCH CONSENT FORM

Title of Study: Health Information for Infected Veterans (HI-FIV)	
Title of Consent (if different from Study Title): Consent for Veteran Interview	
Principal Investigator: **Amanda Midboe, PhD**	VAMC: VA Palo Alto HCS

What is this research about?

You are invited to participate in a voluntary research study of My HealtheVet (MHV) use by Veterans and VA providers/staff who care for them. We hope to learn and understand how MHV can improve the self-management of chronic conditions. Your involvement will be to participate in an interview that will last between 20 to 60 minutes.

This research study is looking for 60 Veterans and 30 VA providers/staff in the United States. The VA Palo Alto expects to enroll a total of 90 research study subjects.

What is expected of me? What are the study procedures?

If you choose to participate, a research team member will contact you to participate in a one-time audio-recorded interview over the telephone or in person for 20 to 60 minutes. The purpose of the interview is to figure out why certain patients and provider/staff use MHV the way they do, understand any technical MHV issues, and learn about attitudes and perceptions that may prevent others from using MHV. The research staff may ask you questions about self-management, including appointment attendance, preventive health care, management of other common comorbidities, refilling medications, medication adherence, etc.

This interview will be audio-recorded, so the researchers can review and summarize your responses. You will be asked to provide verbal consent to give us permission to voice record you as part of the research study. This audio recording will be used for this research study only and will not be disclosed outside of the VA. The recording will be typed word-for-word by so that we can analyze what is being discussed. If you do not wish to be audio-recorded, but want to participate in the study, the study staff will take notes instead.

What are the possible risks or discomforts?

This study involves the following risks, discomforts, and possible inconveniences:

The risk of taking part in this study is small. Some of the questions in the interview will ask you about self-management, including appointment attendance, preventive health care, management of other common comorbidities, refilling medications, medication adherence, etc. These may have the potential to cause you distress, although we do not anticipate this. Your answers will be kept confidential, but there is a small risk that people outside of the research team could learn the information. We will make our best effort to protect your information and privacy

Will I benefit from the study?

You will receive no direct benefit from participating in this study. The information we learn from this study will help us better understand how to communicate with and provide care for Veterans with chronic disease. We hope this knowledge will contribute to improving care for Veterans with chronic disease.

What are my alternatives to being in this study?

Your participation in this study is completely voluntary. This is NOT a treatment study. You can receive treatment without participating in this study. The alternative to participating is to choose not to participate. If you decide to participate, you can change your mind at any time or refuse to answer any questions. You will not lose any benefits if you choose not to participate. Your choice to participate or not will not impact your care. Your care will not be affected if you choose to withdraw from the study at any time.

Will I get paid?

After you complete the telephone or in-person interview, you will be compensated $25 for your time and effort in the form of a check or direct deposit. You will need to provide your social security number and address to receive payment.

Will I have to pay anything?

You will not have to pay anything to be in this study.

Do I have to be in this study?

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

Can I change my mind later and stop being in this study?

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We will keep your name and all the information about you used in this study as confidential as possible. We may publish the results of this study for others to read, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information if they decided to audit us.

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- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

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Department of Veterans Affairs

RESEARCH CONSENT FORM

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Principal Investigator: **Amanda Midboe, PhD**	VAMC: VA Palo Alto HCS

STUDY INFORMED CONSENT

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Do you give your verbal consent to be audiotaped during this study? ___Yes ___No

Providing your verbal consent means you agree to be in this study.

_____ _____
Print Name of Participant *Date & Time*

_____ _____
Signature of Person Obtaining Consent *Date & Time*

_____
Name of Person Obtaining Consent