Participant Name: _____ Date:_____

Title of Study: A nurse-led intervention to extend the Veteran HIV treatment cascade for cardiovascular disease prevention (V-EXTRA-CVD).

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: _Dr. Hayden Bosworth, PhD_____

KEY SUMMARY INFORMATION ABOUT THIS STUDY

This study is about understanding the usefulness of a nurse/pharmacist -led intervention in improving blood pressure control for patients living with HIV. You are being invited to take part in this research study, which is being funded by the Department of Veterans Affairs HSR&D service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The study will test a VA adapted nurse/pharmacist-led intervention to reach cardiovascular (CVD; heart) guideline targets. Veterans who agree to participate in the study will be assigned to one of two groups. These are the Nurse/pharmacist-led intervention group and the Education Control group. The intervention will consist of four evidence-based components adapted to veterans with HIV: (1) care coordination, (2) medication protocols and adherence support (3) home blood pressure (BP) monitoring, and (4) electronic medical records (EMR) support tools. The intervention will be administered using the VA telehealth technologies of VA Video Connect and ANNIE Short Message Service (SMS). The education control will receive enhanced CVD prevention education plus usual care from their providers.

If you choose to participate, your participation in this study will last about 12 months. After enrollment in the study, you will be selected by 50/50 chance to receive either the nurse intervention or the education control group. By doing this study, we hope to learn how to better manage blood pressure and blood lipids in Veterans living with HIV.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

This study may help lower your blood pressure and lower your risk for heart disease. Since veterans with HIV have a higher risk for heart disease than those without HIV, this study could help your overall health. For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The most important reason you might not join this study is if you do not want to participate in nurse/pharmacist-led blood pressure and cholesterol management by telehealth. For a complete description of the risks, refer to the Research Details.

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PI/SC Approval Date:

LSI Approval Date:

LSI Verification Date:

Participant Name: _____ Date:_____

Title of Study: A nurse-led intervention to extend the Veteran HIV treatment cascade for cardiovascular disease prevention (V-EXTRA-CVD).

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: _Dr. Hayden Bosworth, PhD_____

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is <enter site PI and site name> . If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:<enter phone number for site PI> .

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research is to improve the cardiovascular health of Veterans living with HIV. This is a multisite project being conducted at 4 VA Health Care Systems (Durham, NC; Baltimore, MD; Atlanta, GA; and Cleveland, OH). It will involve veterans who are living with HIV on suppressive antiretroviral therapy (ART) with poor blood pressure control and who have a regular infectious disease (ID) or primary care provider (PCP) at one of the 4 sites. By conducting this study, we hope to learn how to help patients living with HIV manage blood pressure and cholesterol levels better and lower their heart disease risk. We know that veterans living with HIV are at a higher risk for heart disease, almost double the risk of people who are not HIV-positive. While you have taken medication to manage your HIV, we now want to focus on better controlling your blood pressure and cholesterol levels. These 2 things can help lower your risk for heart disease in the future.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3 years. Your individual participation in the project will take 1 year or 12 months. We will enroll 300 veterans for this study and will ask each to be in the study for 12 months. We plan to enroll 25-125 veterans with HIV at each site: Durham, NC, Baltimore, MD, Atlanta, GA, and Cleveland, OH.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you agree to participate in this research study, you will be asked to sign this consent form. This study involves four (4) in-person research visits and one (1) optional audio-recorded phone interview at the end of the study. You will receive education information about controlling your

blood pressure and blood cholesterol levels and may also have telehealth visits with the study nurse, who is located in Durham, NC, or the pharmacist, who is located in Baltimore, MD. If you do not enroll, your Infectious Disease (ID) or primary care provider (PCP) will manage your care as usual.

During your year of participation in this study, we ask that you do not participate in any other similar interventional research studies related to blood pressure or cardiovascular disease.

Visit 1: ***(today)***
At the first visit, the research assistant (RA) will take 3 blood pressure readings and measure your height, weight, and waist circumference. If an error occurs when we are measuring your blood pressure and we are unable to obtain your blood pressure during the 3 readings, we will take up to three more readings for a maximum of 6 readings. The RA will then ask you a series of questions covering topics such as: demographic information, health and lifestyle, physical activity, technology and medication use. You are always free to skip any questions that you prefer not to answer. We will also ask if you have a blood pressure monitor for home use, and will place an order if you do not already have one. We will place orders for you to visit the lab where they will draw your blood to collect about 2 teaspoons to check your cholesterol levels. Your blood samples will be discarded after the test is complete. You do not have to fast for this blood test. At the end of the study visit you will be randomly assigned using a procedure, like flipping a coin, to one of the two groups. There is a 50/50 chance of being placed in either of these groups:

- **Nurse/pharmacist-led intervention group**
- **Education control group.**

The **Nurse/pharmacist-led intervention** includes guideline-based medication adjustments, as well as behavioral education information, to address the different ways of improving your blood pressure and blood cholesterol levels. Every 2 months, the “health coach” (a nurse or pharmacist trained for this study) will contact you to talk about your blood pressure and cholesterol levels and how to improve them and lower your risk of heart disease. These calls will typically take about 20-30 minutes.
You will receive regular calls from the health coach, using VA Video Connect. When the health coach contacts you, she will review your blood pressure and cholesterol medications and will give you a personalized medication schedule showing you when to take each medication. During these calls, the health coach will also discuss topics related to heart health, like diet, physical activity, smoking cessation, and alcohol misuse. If relevant, your health coach can also make referrals to VA clinics or programs that would help in these areas. The goal of these video calls is to help lower your risk for heart disease and improve your blood pressure. Your first call with your

health coach will be during this first week of the study. After this first call, your health coach will continue to call you on a regular basis – about every 2 months. More frequent calls (up to every 2 weeks) may occur if you change medications or if your blood pressure is not at goal.

This intervention uses 2 telehealth technologies that are part of normal clinical care – VA Video Connect and Annie. VA Video Connect is a way to have videoconference, or virtual visits with your health coach. Annie is a computer system that sends you personalized text messages to remind you to complete health tasks. In this study, we will want to know your home BP readings, and you can send the results to us using text messages through Annie. We will review the Annie consent form before signing you up for the program. Your cell phone number and/or email address will be required to use the telehealth modalities of VA Video Connect and Annie. Both technologies will use your own smartphone, tablet or computer. If you are unable or unwilling to use VA Video Connect for the calls with the health coach, they may call you on the telephone. The calls with your health coach may be recorded for quality control – the coach would ask your consent to be recorded, and your name will not be listed on the recording. You may also be asked to bring your blood pressure monitor with you every 4 months when you return for your scheduled in-person visit.

The **Education Control group** will receive CVD education materials. Your primary care and management of CVD will continue as it normally would from your own provider. The education control group will not have contact with the health coach.

You will be paid $50 at the conclusion of this visit once the lab draw is completed. This payment will come by a method determined by VA policy and may be an electronic fund transfer, a VA check, or another form of VA payment. Today's baseline visit for the study should take approximately 2-3 hours.

VISITS 2 and 3: ***(4 months, 8 months)***
Four (4) and eight (8) months later, all participants will be asked to for follow-up research visits. At these visits, we will measure your blood pressure, weight, and waist measurements again. You will also be asked some of the same questions as in the initial visit: about your understanding of cardiovascular disease, and changes you have made in your weight, smoking status, medication adherence or other lifestyle factors.

If you were assigned to the Education Control Group, we will provide additional educational information on heart health. At the conclusion of the visit you will be directed to the lab for a repeat blood draw following the same procedure as described for visit 1. You will be paid $25 at the conclusion of each of these visits once the lab draw is completed. Payments will be made via VA policy as previously described. This visit should take approximately 1 hour

VISIT 4: (*12 months)*

The fourth and final in-person visit is 12 months after you consented to participate in the study. In addition to having your blood pressure, weight, and waist measurements recorded, you will be asked questions about your understanding of cardiovascular disease, and changes in your weight, smoking status, medication adherence and other lifestyle factors. If you received the Intervention, we will ask about your thoughts regarding the intervention. If you were assigned to the Education Control Group, we will ask about your thoughts concerning the information on CVD reduction you received. At the conclusion of the visit you will be directed to the lab for a final blood draw (checking cholesterol levels) as described for visit 1.

This final in-person visit should take approximately 1 hour. You will receive $50 after completion of this visit once the lab draw is completed. Payments will be made via VA policy as previously described.

Overview of study components:
In-person visits (for all participants)

	Baseline visit	4 month visit	8 month visit	12 month visit
BP, height*, weight and waist measurements *height is only measured once, at the baseline visit	X	X	X	X
Blood drawn to measure cholesterol	X	X	X	X
Health-related questionnaires	X	X	X	X
Payment	$50	$25	$25	$50

Telehealth calls/visits with health coach (for intervention participants only)

	Week 1	Week 2	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12
Review home BP	X	X	X	X	X	X	X	X
Review medications	X	X	X	X	X	X	X	X
Lifestyle education	X	X	X	X	X	X	X	X

OPTIONAL STUDY PROCEDURES

Optional audio recorded phone interview:

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If you are selected for the Intervention, it is possible that we may ask to speak with you at the end of the study to discuss your participation. This interview is optional. The questions we ask would focus on your opinion about different parts of the intervention. The conversation will be audio recorded on a VA-owned and configured computer or approved device. Your name will not be associated with the audio recording, and your consent to be recorded will be captured on the recording. The conversation will be later written down using VA-owned computer software, and the recording will be destroyed in accordance with the VA Records Control Schedule. This is an optional part of the study and you have the right to refuse to participate in it. However, if you do not agree to be audio recorded, you cannot participate in this part of the study. Those agreeing to participate will be scheduled to complete the qualitative interview within 30 days from the time they complete the intervention and the final in-person interview.

This phone call for the optional qualitative interview should take no more than 30 minutes. You will be paid $20 for completion of the optional qualitative phone interview, which will be paid via VA policy as described above in visit 1.

Would you like to be contacted at the end of the study to participate in the audio-recorded optional opinion type questions about the Intervention if you are selected for that group?

____ Yes, I want to be contacted and agree to be audio recorded.
____ No, I do not want to be contacted.

_____Initials

Participant Support group:
If you are selected for the intervention group, you will have the option to participate in monthly, virtual, support groups to talk with other Veterans in the study. These will be monthly “drop-in” groups that you can participate in using your computer. For any Veteran randomized to the intervention arm, you are welcome to attend the groups while you are still enrolled in the study. The groups will be for approximately 60 minutes and will be organized by a member of the study team who will function as a facilitator during the session. The purpose of these groups is for the Veterans to talk with one another about their experiences, struggles and challenges in managing their blood pressure. The groups will not be used to seek or obtain medical advice from a medical professional. Sessions will be conducted using a VA-approved videoconferencing platform, such as Cisco Webex or Microsoft Teams, when possible, or by phone, when needed. These sessions may be recorded for quality control purposes only. A link will be emailed to you for each meeting if you would like to attend. If you are unable to access the online meetings (requiring internet), the team can provide a phone number for you to call in to the meeting.

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Would you like to be invited to the monthly virtual support groups if you are selected for the intervention group?

____ Yes, I am interested in participating in the support groups and agree to be audio recorded.

____ No, I do not want to be contacted about the support group.

_____Initials

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your in-person study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- If assigned to the intervention group: please keep your VVC/phone appointments with the health coach and follow all instructions for sending in your home blood pressure readings.
- If assigned to the intervention group: please let the study team know if your phone number or email address changes during the course of the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

At the end of the study participants will receive a report of the research results containing an overview of the summarized data of all Veterans participating in the study. No individual study results will be part of this overview.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur. We do not anticipate significant physical risks from participating in this study.

- The health coach may refer you to programs involving exercise or physical activity which could result in discomfort; however, these programs are already endorsed by the VAMC and your primary care team will be aware of your enrollment.
- You may experience some pressure or feelings of discomfort during the blood pressure measurements.
- The risks of having blood taken from a vein in your arm are pain, bleeding, bruising, and rarely, infection at the site where the needle is inserted. Fainting or light-headedness may occur, but this is also rare. To reduce this risk, a trained phlebotomist from the hospital lab will draw your blood. If you are injured as a result of having blood drawn, VA will provide medical treatment for your research-related injury at no cost to you.
- The study intervention is likely to encourage you to try new foods and increase exercise. This may lower glucose levels and raises the possibility of allergic reactions.

It is possible that you may feel uncomfortable answering some of the questions on the surveys, such as questions about your health, race/ethnicity or socioeconomic status. We will only ask questions that are important to our study, and you may skip any questions that make you feel uncomfortable.

Since personal data will be collected as part of this study, there is a risk of loss of confidentiality. If information about you does leak out, VA will not be able to guarantee that it will be protected. However, we will make every effort to protect your confidentiality and to make sure your identity does not become known. All electronic information will be stored in a secure manner per VA Information Security Policy. All written information will be stored in a locked file cabinet. Only a few authorized VA staff assigned to this study will know your identity.

The management of blood pressure and lipids during pregnancy are different than those in non-pregnant individuals, so you may be ineligible if you are pregnant or trying to become pregnant. If you become pregnant, you must inform a member of the study team, and we can assist with referring you to VA Obstetrics for follow up if necessary. At that point we will have to remove you from the study.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect. Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include an improvement in your blood pressure and/or cholesterol levels, and a lower risk of developing heart disease. Additionally, the information we get from this study may help other veterans living with HIV.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you do not want to join the study, but are interested in improving your heart health, you can ask your primary care provider about other relevant VA programs/clinics. This could include the MOVE program, smoking clinic, or appropriate mental health clinics.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- All research records that include personal information (names, signatures) will be kept locked in filing cabinets, on computers protected with passwords, and can only be accessed by members of the study team.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

We will include information about your study participation in your medical record. Your primary care provider will know that you have enrolled in the study and will be able to see the results of any bloodwork (when we check your cholesterol levels), or any changes in medication.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

It is possible that information collected from this study will be used for future research studies. If this is done, anything that identifies you will be removed from the data collected before being used. You will not be contacted again to consent to this additional use of information.

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Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate), the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related (Outcome blood pressures and survey results) 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.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility o you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Hayden Bosworth, PhD** and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Study payments:

You will be eligible to receive payments if you enroll in this study. You may receive up to $170 for participating in this study. The payments are listed below:

- In-person visits at month 0 (today) and month 12: $50 each
- In-person visits at month 4 and month 8: $25 each
- (optional) interview at study end about your experience: $20

The research assistant completing the visits with you will submit the payment voucher following each visit. If you are enrolled in direct deposit, you should receive your study payment within a few weeks. If you are not enrolled, the process to receive a check to your home address may take 6-8 weeks. Please note that your social security number will be used to process your payment, and these payments may generate Internal Revenue Service Form 1099.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

There is no compensation available should an injury occur. By signing this form, you do not give up any legal rights or release the VA from liability.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: <enter site PI name and daytime number>
AFTER HOURS: <enter site PI name and evening contact number>

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LSI Verification Date:

Participant Name: _____ Date:_____

Title of Study: A nurse-led intervention to extend the Veteran HIV treatment cascade for cardiovascular disease prevention (V-EXTRA-CVD).

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: _Dr. Hayden Bosworth, PhD_____

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in any research study is voluntary. Refusing to participate will not change your benefits at the VA. If you are a VA employee or student, refusing to participate in this study will not change your employment, ratings, recommendations, or academic progress.

If you do choose to participate in this study, you may withdraw at any time. If you withdraw, you will still receive the same standard of care that you would have otherwise received. We do ask that you contact the study team if you are considering withdrawing from the study. You may still be eligible to participate in the outcome assessments (in-person visits) even if you withdraw from the nurse-led intervention (for those assigned to the intervention group).

If you do withdraw from the study, please understand that any information or samples collected from you will still be used in the study analysis. You cannot withdraw information already collected, but you can withdraw from future study visits and data collection.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

It is possible that the site Principal Investigator (<enter site PI name>) may withdraw you from the study without your consent. This would only happen if the investigator believes it to be in your best interest, generally for health or safety concerns.

Your participation may be terminated without your consent for one or more of the following reasons:

- The study is suspended or cancelled.
- You display abusive behavior toward the staff
- You are female and become pregnant during the study

Taking part in this study is your choice. You have the option not to participate. If you choose not to participate, you still have the option of or participating in any other program to which you are eligible.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about this research study, you may call <enter site PI name and contact number>

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Participant Name: _____ Date:_____

Title of Study: A nurse-led intervention to extend the Veteran HIV treatment cascade for cardiovascular disease prevention (V-EXTRA-CVD).

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: _Dr. Hayden Bosworth, PhD_____

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

<enter site PI name> or his/her staff has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. If required by local IRB/R&D/RCO, a copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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PI/SC Approval Date:

LSI Approval Date:

LSI Verification Date: