Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Karen Ingersoll Ph.D., Licensed Clinical Psychologist Behavioral Health and Technology Department of Psychiatry and Neurobehavioral Sciences University of Virginia 560 Ray C Hunt Drive; Office #3147 Charlottesville, VA 22903 Phone: 434-982-5960
Sponsor	National Institute on Drug Abuse (NIDA), which is a branch of the National Institutes of Health (NIH).

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded by National Institute on Drug Abuse (NIDA), which is a branch of the National Institutes of Health (NIH).

Why is this research being done?

Background:

There are many reasons why people living with HIV struggle with taking their antiretroviral therapy (ART). Taking antiretroviral medications as prescribed is called Adherence. Research has shown that patient-centered approaches work well for dealing with adherence issues; however, there are numerous barriers to HIV medication adherence such as lacking social support, depression, fear, stigma, risky drinking and substance use. Interventions may be used to help patients take action and use strategies to improve their situation and to overcome barriers in order to take their antiretroviral medication daily.

The purpose of this study is to determine if an intervention delivered over the Internet can help people living with HIV take their Antiretrovial Therapy (ART) as prescribed. This intervention is called Peers Offering Support for Health or Pos4Health for short.

You are being asked to be in this study because:

- You are HIV positive and on Antiretroviral Therapy (ART).
- You report ART nonadherence in the past 30 days
- You may be drinking at risky levels or using drugs in the past 30 days
- You are at least 18 years old.
- You can speak and read English.
- You can provide meaningful informed consent.
- You are willing to be followed for 4-5 months.
- You have an email address.
- You have regular access to a computer, the Internet, and telephone

Up to 80 people will be in this study at the University of Virginia (UVA). However, you are not required to physically come to UVA to participate. **The intervention is completed entirely online.**

How long will this study take?

Your participation in this study will take about 15 weeks. During the course of the study, your time commitment will include the following:

- Completing a 45 minute phone screening to review this consent form and ask you additional questions about taking your HIV medication (ART), your use of cigarettes, alcohol, and illicit (street) drugs over the past 30 days to ensure this study is appropriate for you.
- Completing a 60 minute online Questionnaire at 2 different times:
    - On the 1st day you enroll (baseline)
    - 9 weeks after you start the study (post-assessment)
- Completing 2 weeks of Pos4Health Diaries (10 entries within 14 days)* at 2 different times:
    - After completing the Questionnaire during the first week (baseline)
    - After completing the Questionnaire at 9 weeks (post-assessment)

**The diary is an online form that takes 2-3 minutes to complete. Questions ask about HIV medication use, smoking, drinking, and drug use, your mood, and if you tried a tip.*

- Completing a second 45 minute phone interview about your HIV medication, smoking, drinking, and drug use since your initial phone screen (post-assessment).

- ***If you are assigned to the* Pos4Health *Internet intervention:***
    - During the 9 week study intervention period, the Internet Intervention will take approximately 1 – 2 hours of your time each week.
    - After that, there are no specified time requirements for using the Internet intervention.
- ***If you are assigned to the* Pos4Health *information website*:**

- You can review the content of the website at any time during the 9 weeks, with no set time commitments.

The Pos4Health website (both intervention and information) will remain active until the end of the study grant funding meaning you may continue to review your assigned website if you wish.

What will happen if you are in the study?

SCREENING (will take about 45-60 minutes to complete):

Prescreening (15 minutes):
You have already reviewed and signed the **Consent to Provide Information Over the Internet Consent Form** and answered questions on the Interest Form on the study website (www. Pos4Health.org)

Screening (45-60 minutes):
Before you can start in the study, there will be an additional screening session over the telephone. During this session, you will first review and sign online the study consent form. Then you will complete an interview asking some additional questions to make sure you are eligible and it is safe for you to participate. These include:

- *Collecting your daily HIV medication, smoking, drinking, and illicit (street) drug use behaviors during the past 30 days.*

Steps:

1. During the telephone call, the Study Coordinator will ask you to identify yourself. The Study Coordinator will review the criteria for enrollment in this study and the study's requirements. At that time, you can discuss any questions or concerns you may have about participating in the study.
2. If you agree to participate, you will e-sign the consent form before any further study related procedures take place.
    a. You will be emailed a unique website address to access the online consent form system.
    b. You will review this consent form with the study coordinator on the telephone.
    c. When you feel comfortable and ready to sign, you will use your mouse to draw your signature at the bottom of the electronic version of this form.
    d. Once you click submit, the program will email you a signed copy of the consent form with your electronic signature. We will store the document in our database as well.
3. After you have successfully consented to participate in the study, we will continue with the phone screen. The Study Coordinator then will review a calendar of the past 30 days and collect data on behaviors, including HIV medication, and tobacco, alcohol, and illicit (street) drug use for the past 30 days.
4. We may learn during this call that you are not eligible for this study. If so, you will be informed.
5. After the phone screen is complete, if you are eligible, you will be emailed your unique login identification number and password to start participating in Pos4Health.

PRE or BASELINE ASSESSMENT (60-90 minutes)

- Using your ID number and password, you will access the study website (www.Pos4Health.org) and log in to the program.

Questionnaire:

- You will then complete an online Questionnaire. These questions will take about 1 hour to fill out. The questions are about your general health, mental health, internet use, HIV, HIV medication, and use of alcohol, tobacco, and drugs, and lifestyle habits. If you have any concerns about the questions, please contact the Study Coordinator.
- Study personnel have no plans to review your questionnaire responses during the study and if you report a problem on your questionnaire, we will probably not know about it until after the study ends. Please answer honestly, but if you are suicidal or if you need to report another crisis situation, you should contact the clinic and ask to speak with a member of your health care team.
- You can complete the Questionnaire in more than one sitting. The program auto saves your results. You can review and revise answers up until the point you click "Submit." Once it is submitted, you will no longer have access to your responses on the Questionnaire.
- You will receive 2 system-generated reminder emails to complete the Questionnaire. You may also be reminded by the Study Coordinator via email or phone.
- Once you press "Submit", the program automatically advances you to the Diary phase of the Assessment. At that time, you will begin keeping online Daily Pos4Health Diaries reporting HIV medication use, mood, tips tried, number of standard drinks consumed and cigarettes smoked, and type of illicit drugs used each day. This is a short form that takes 2-3 minutes to enter each day.

Diary:

- You will be asked to complete these Pos4Health Diaries every day for two weeks. You will receive daily reminder emails to complete the Pos4Health Diaries.
- After you have completed the Questionnaire and entered 10 Pos4Health Diaries in 14 days, the program automatically advances you to your assigned website. At that time, you can then log in to the study website and begin using your assigned website.

Your Medical Records:

- A member of the study team will review your medical records to collect your current immune health markers from laboratory visits such as CD4 count, viral load, pharmacy prescriptions and refill rates, medication type and dosing schedule. If you use the UVA ID Clinic, we will have access to your records. If you use another clinic, we will ask you to sign a medical release form from your doctor and pharmacy to provide us with your current immune health markers. Additionally, we will ask you to sign a release of information to request pharmacy refill records if you use a pharmacy outside of UVA. This release will give us permission to request your past 6 months of pharmacy refill information from all the pharmacies you use for your HIV medications. In some cases, pharmacies require their own consent for release of information, and if that happens, we may request that you sign that special form in addition to the general UVA release of pharmacy information form.

RANDOMIZATION and STUDY TREATMENT (9 weeks)

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to either group. Neither you nor the study leader can choose the group you are assigned.

Both Groups will gain access by going to www.Pos4Health.org and logging in with their ID and password.

GROUP 1: Pos4Health Information Website: You will use a website with information about HIV, HIV (ART) medication, and strategies for coping with barriers to ART adherence such as depression, stigma, disclosure, social support, and using drugs, alcohol, and cigarettes.

GROUP 2: Pos4Health Internet Intervention: You will use an interactive Internet program, Peers Offing Support for Health (Pos4Health), which is designed to help you improve your HIV medication adherence by managing barriers to treatment such as depression, stigma, disclosure, social support, and using drugs, alcohol, and cigarettes. You will complete Cores and enter Pos4Health Diaries into the online program.

If you are assigned to Group 1:

- You may log into the program and read the content as often as you like.
- There are no specific time requirements.

If you are assigned to Group 2:

- You will be asked to complete six Cores or units (main Pos4Health content) during the 9 week intervention period. Pos4Health is designed to help you improve your HIV medication adherence by managing barriers to treatment. You will gain access to one Core at a time. After completing a Core, you will spend a week practicing what you have learned in the completed core. The next week (7 days later), a new Core becomes available. Each Core contains information and exercises designed to help you develop new habits and skills.
- A Core is expected to take 45-60 minutes to complete online. Reviewing and following the core recommendations will take most participants another 60 minutes per week.
- You will receive automated email prompts encouraging you to return to the site.
- You will be encouraged to keep regular online Pos4Health Diaries throughout the intervention period.

FOLLOW UP:

POST-ASSESSMENT at 9 weeks (60-90 minutes):

Questionnaire:

- At the end of the 9 week intervention period, you will be instructed (by email) to complete the Post-Questionnaire. The Post-Questionnaire has many of the same questions you answered at the beginning (like questions about your general health, mental health, internet use, HIV, HIV medication, and use of alcohol, tobacco, and drugs, and lifestyle activities), but there are fewer questions. This is estimated to take 1 hour to complete.

- You can complete the Questionnaire in more than one sitting. The program auto saves your results. You can review and revise answers up until the point you click "Submit." Once it is submitted, you will no longer have access to your responses on the Questionnaire.
- You will receive 2 reminder emails to complete the Questionnaire. The study coordinator may also remind you by email or phone.

Diary:

- Once you press "Submit", the program automatically advances you to the Diary phase of the Assessment. You will be asked to complete these Pos4Health Diaries every day for two weeks. You will receive daily reminder emails to complete the Pos4Health Diaries.
- You will keep Pos4Health Diaries reporting HIV medication use, mood, tips tried, number of standard drinks consumed and cigarettes smoked, and type of drugs used each day. This is a short form that takes 2-3 minutes to enter each day.

Phone Interview for HIV medication and substance use:

- You will schedule a phone interview with the study coordinator. During the interview you will review your HIV medication, tobacco, alcohol, and drug use in the past 30 days. The phone interview is estimated to take 45 minutes.

Your Medical Records:

- A member of the study team will again review your medical records to collect your current immune health markers from laboratory visits such as CD4 count, viral load, pharmacy prescriptions and refill rates, medication type and dosing schedule. If you do not use the UVA ID Clinic, we will ask you to again provide us with this information. You have already signed a release of information form at the beginning of the study.

Study Schedule

	Screening	Pre-Assessment (Baseline)	Intervention Period	Post-Assessment (End-of-Study)
Study Week	0	1-2	3-12	13-15
Informed Consent	X			
Review Study Eligibility	X			
Phone Interview – TimeLine Follow Back	X			X
Questionnaires		X		X
Diaries		X		X
Medical Record Review		X		X
Assigned Study Group			X	
Follow-up Questionnaire				X

END OF STUDY:

- After completing the Post-Assessment, participants will have continued access to their online program until the end of grant funding.
- After completing the Post-Assessment, participants will have the option to use the other version of the website that they were not assigned to during the trial.

FOLLOW-UP QUESTIONNAIRES:

You may be invited to share your feedback on the study with the study coordinator. This questionnaire will focus on your rating of how easy it was to use the program, usability issues, or technical support needs. We will explore reasons for not completing sections or for reviewing some elements repeatedly. You may offer suggestions for improvement. The questionnaire will take about 5 minutes.

Three groups of subjects may be contacted for follow-up questionnaires:

- Completers – subjects who completed assessments and Cores
- Non-completers – subjects who did not complete assessments or Cores
- Refusers – subjects who do not enroll in the study after completing an Interest Form

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given including logging onto www.Pos4Health.org to complete questionnaires, diaries, and Cores (if assigned).
- You should tell a study staff member about any changes in your health or the way you feel. However, if you need to report a crisis situation, contact your health care team.
- Answer all of the study-related questions completely.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to your participation in this study include:

Rarely:

- There is a small risk that someone could see your private information. However, information collected from you over the Internet will be obtained through secure means and stored on our private servers. All data on our servers are password protected and limited to members of the study team.

Infrequently:

- Internet concerns: Although some adults may feel more comfortable providing information over the Internet, others may feel less comfortable with this process and have concerns about the confidentiality of their digital data.
- Discomfort answering questions of a personal nature.

Likely

- Feeling temporarily upset or frustrated about some of your habits

Less Likely

- Possible distress about your own personal habits

Protection against risks:

Breach of privacy concerns: Data collected from you over the Internet will be obtained through secured means and stored on our private servers. All data on our servers are password protected and limited to authorized research personnel. The only private identifying information that is stored in the application is your email address. The high-level architecture of the system allows us to separate all other identifying and non-identifying data. We have worked out a system in which two servers have been set up with one private server configured behind the firewall where secured data resides and only individuals who have access onsite are able to connect to this server. A second server maintains the front-end web system so that you can access the system. Data submitted by you is captured and transferred to the secure server.

<u>Risks from Completing Questionnaires</u>

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them.

- Some of the questions asked may make you angry, emotionally upset or stressed out now or at a later time. If this occurs, you can contact ***Dr. Ingersoll, the Principal Investigator, at kes7a@virginia.edu*** for help.
- There could be a risk of discomfort and harm (to psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation.
- You may answer questions about your experiences including emotional or mental health problems, such as feelings of depression or thoughts of suicide. Please do not use these questions as a way to get help, because the study team may not review the answers until the end of the study. Please feel free to answer truthfully, but if you are depressed, have thoughts of suicide, or other problems, please contact your clinic and your health care team for help.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?
You may or may not benefit from being in this study. Possible benefits include: increased awareness of your HIV medication adherence and behaviors that may impact your health and ART adherence. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?
You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include your usual care as prescribed by your doctor.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?
You will be paid up to $150 in online gift cards for finishing this study according to the following:

- $50 after you complete the Baseline Assessment (questionnaire, 2 weeks of diaries, and interview)
- $100 after you complete the Post Assessment (questionnaire, 2 weeks of diaries, and interview)

Follow-up Questionnaire

- $10 If you complete a follow-up questionnaire

All payments will be sent via email within a week of completing each assessment. If you do not use the UVA ID Clinic, and do not provide us with your current immune health markers and pharmacy information, you will not be given payment for that assessment. You will not be paid if **you** decide not to finish this study. However, if the study leader decides you should not continue, but you met full criteria and completed the necessary steps in the timeline presented, you will be paid the full amount for the study. The income may be reported to the IRS as income.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

Will being in this study cost you any money?

Being in this study will not cost you any money. Your insurance company will not be billed either. However, the costs associated with use of a computer or the Internet will not be paid for by the study.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

- d) New information shows the treatment will not work or is not safe for you
- e) You do not follow your doctor's instructions
- f) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to notify us by calling (434)982-5947, or by emailing Dr. Karen Ingersoll, the principal investigator of this study at kes7a@virginia.edu or Kirsten MacDonnell, the study coordinator at kem6e@virginia.edu.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This

may include pharmacy records, mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

We have a Certificate of Confidentiality issued by the federal government, to help protect the privacy of your study records. If we receive a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVa will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.
- Reports to authorities if you have an infectious disease that health care providers are required to report by law.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy. This Certificate will not protect your information if you give permission for your

insurance company, employer or another person to see your records. It also may not protect your information if you tell other people that you are in this study. To protect your privacy a copy of this consent form will not be put in your medical record, if any, at UVA. (This is not the same as the record of this research study.)

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Karen Ingersoll Ph.D.
Behavioral Health and Technology
Department of Psychiatry and Neurobehavioral Sciences
University of Virginia
560 Ray C Hunt Drive; Office #3147
Charlottesville, VA 22903
Phone: 434-982-5960

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE