UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

This study is also approved by the Florida Department of Health IRB. If you want to talk with someone independent of the research team for questions, concerns, or complaints about the research; questions about your rights; to obtain information; or to offer input, you can contact the Florida Department of Health Institutional Review Board. An Institutional Review Board is a group of people who review research to ensure participants are protected and the research is conducted in an ethical way. You can contact the IRB at: 850-245-4585

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Laboratory and field validation of a wrist-worn alcohol monitor

3. Who do you call if you have questions about this research study?

Principal Investigator: Yan Wang, PhD, ywang48@ufl.edu, (352)294-5942
After hour phone number: (352) 214-4047 (text or call)

4. Who is paying for this research study?

The sponsor of this study is NIH (NIAAA).

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to validate a newly-developed wrist-worn alcohol monitor and see how accurate and reliable it is. We also wanted to find out whether this monitor works the same for HIV+ and HIV- drinkers. We expect you to be in the study for approximately three months.

b) What is involved with your participation, and what are the procedures to be followed in the research?

Your participation will first include an initial screening appointment to establish your eligibility status. If eligible, you will be asked to wear a wrist-worn alcohol monitor during 1) an initial alcohol drinking session; 2) a two-week field-use period on your own; and 3) another alcohol drinking session identical to the initial drinking session.

c) What are the likely risks or discomforts to you?

Some potential risks for you include breach of confidentiality; health risks from drinking alcohol; and maybe uncomfortableness in answering some questions.

d) What are the likely benefits to you or to others from the research?

There are no direct benefits to you as a participant, although the wrist-worn alcohol monitor may provide information regarding your drinking behaviors and patterns that you may find useful. Others may benefit from the information you provide us regarding how accurate the alcohol monitor is and whether it can be a useful tool for changing unhealthy drinking behaviors.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

No clinical care is provided. Your participation is for research purposes only, and not to treat or diagnose any disease. Should you choose not to take part in this study, we can give you information about programs (research and internet) that can help you reduce your drinking if you are interested.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this 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 CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

"Normal Clinical Care" means procedures that would normally be used as part of the treatment for patients with a particular problem. No clinical care is provided. All of your participation is for research purposes only, and not to treat or diagnose any disease.

7. What will be done only because you are in this research study?

This study will include two parts: wearing a wrist-worn alcohol monitor called BACtrack Skyn (BACtrack Inc.) when you come to our lab to drink 3 beers, and for two weeks in your daily life. The diagram below gives you an overview of what you are expected to complete during the study period. You will be invited to complete either all components of the study or only the field test portion given the COVID pandemic.

Briefly, you will first go through a screening to make sure you qualify. Then you will complete an alcohol drinking session (Lab Session 1) at a simulated lab located in Yon Hall, University of Florida, where you will consume 3 standard drinks (i.e., 3 12oz beers) at the pace of 30min per beer. The readings collected from the Skyn monitor will be compared with your breath alcohol concentration (BrAC). After completing Lab Session 1, during a two-week field test, you will wear the monitor and record drinking episodes using an app called mEMA (ilumivu, Inc.). After the field test, you will return to the bar lab to complete a second alcohol drinking session using the same procedures as in Lab Session 1. You will also complete a questionnaire about your experience with the Skyn monitor and its smartphone app.

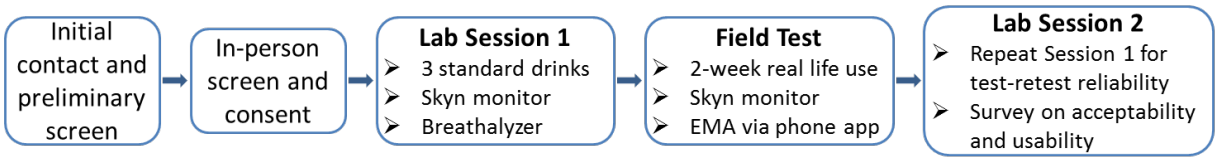

Figure 1. Overview of the study procedures

Screening and consent:

The initial screening appointment will take about 1-2 hours. If asked to complete only the field test, the screening can be done remotely via phone call or password-protected UF zoom or in-person when you come to the lab to pick up the skyn monitor. During this time, we will interview you about your drinking habits, cigarette and other drug use, medical and mental health histories, and menstrual cycle if female. Your vital signs (including blood pressure, pulse, height and weight) will will be collected. You will also be engaged in an interview using a calendar so that we can learn about your recent alcohol use in the past 30 days.

You will also be asked to complete a web-based questionnaire that covers topics including demographics; drinking history; current drinking behaviors; and reasons for drinking.

The alcohol drinking that is part of this study may not be safe for those who are also using cocaine, opiates, phencyclidine, amphetamines, methamphetamine, barbiturates, methadone or benzodiazepines. For this reason, you will not be able to participate in the study if your urine test indicates use of one or more of these drugs (Not applicable if only invited to do the field test).

For those who are asked to complete all components of the study, it is also important that participants begin the alcohol drinking session with no alcohol in their system. A positive breath alcohol test at the in-person screening appointment raises concerns that an individual may not be able to present for the session without alcohol in their system. Participants who arrive with a positive breath alcohol reading may be able to remain at our research office until their breath alcohol level declines to 0.00% and then continue with the appointment or reschedule the appointment one time. However, individuals who arrive at an appointment with a positive breath alcohol reading a second time will not be able to continue participation in the study. We will not be able to provide any compensation for any appointment that ends with dismissal due to a positive urine drug test or positive breath alcohol reading.

It is also not safe for women who are pregnant, nursing, or who may become pregnant to take part in the alcohol drinking part of this study. Therefore, women who are pregnant, nurse or sexually active without use of birth control will not be able to participate in the study.

Given that our study aims to compare whether the monitor works the same for HIV+ and HIV- individuals, you may be asked for medical records containing your most recent HIV lab values (CD4/Viral load). You will receive $20 for bringing in your medical records containing your most recent HIV lab values (CD4/Viral load). We will

ask you to do an oral swab for HIV testing if your HIV status is unknown (i.e., you are not in our previous research registry or you don't have a recent lab result to show us).

After completion of the in-person screen, you will receive $10-20 depending on how long the screen takes. If you are completing the in-person screen remotely, you will receive $10 as compensation for using your phone minutes and $10 for completing the first set of questionnaires. You will then receive $10 for coming in to pick up the skyn device and completing the second half of the in-person screen. If applicable, you will have the option of having the skyn device and other study materials mailed to your preferred address. If you are eligible as a result of the in-person screen, we will schedule you for two drinking sessions, with a two-week period in between these two sessions. Or if only completing the field test, we will schedule you for your two-week field use period.

Lab Session 1:

An alcohol drinking session will take place after the pre-session appointment is completed, provided you are eligible and decide to continue in the study. You will be asked not to drink any alcohol prior to coming to the alcohol drinking session. You will also be asked to abstain from food for 3 hours leading up to your session. We will provide you with transportation to the session. We can pick you up virtually anywhere in Gainesville or the immediate surrounding area.

First, you will be provided a light snack (150-200 calories). At this time, we will ask you to wear the Skyn monitor, and may also ask you to wear the Secure Continuous Remote Alcohol Monitor Continuous Alcohol Monitoring (SCRAM) anklet for the duration of the drinking session. The SCRAM anklet is similar to the Skyn device although it is worn around the ankle rather than the wrist. We ask you to wear this widely used monitor to see if the new wrist-based monitor will show similar readings.

Next your vital signs (including blood pressure, pulse, height and weight) will will be collected and a urine drug and pregnancy screening will occur. You will be asked to complete some questionnaires about urge to drink alcohol; mood; amounts of money you would/would not be willing to spend on alcohol; how much you think that alcohol would be difficult to resist; and your wanting of alcohol. ,

Next, the drinking session will begin. We will provide several common beer brands with similar calorie (125-150) and alcohol level (~4.5% ABV) for you to choose from. You will be instructed to wear the Skyn monitor and drink 3 beers by completing each beer in 15 minutes with a 15-minute break in between (30min in total for each beer). During this time, your BrAC will be measured about every 30 minutes. While drinking each beer, you will be unable to consume any additional beverages (alcoholic or nonalcoholic), however will have access to nonalcoholic beverages (e.g., water, juice) during each 15-minute rest period. Following the end of each beer during the 15-minute rest period, you will also complete a brief packet of questionnaires very similar to the one you completed before drinking, except that in addition, you will also be asked about effects of alcohol you may be experiencing at the time. Alcohol administration will be conducted per NIAAA guidelines.

Your access to beer will end following the 90-minute drinking period. When your access ends, you may not order any beers from the research staff and you will not be allowed to purchase any alcohol from the bar. At the end of the 90-minute drinking period, you will give breath alcohol readings about every 15 minutes for the remainder of the session. Every hour you will also complete the same brief packet of questionnaires you completed earlier in the session.

All participants are required to remain in the simulated lab or research office for two hours after drinking and until your breath alcohol drops to the safe level of 0.00%. During this time, you will be provided free Wi-Fi, TV, magazines, snacks and nonalcoholic beverages (e.g., water, juice). Once your breath alcohol level falls to BrAC=0.00%, alcohol monitors will be removed right before your dismissal. You will be provided transportation back home after. This transportation can only be taken directly home. Transportation will be by car unless you reside within a half mile of the research facility, in which case there will be an option for you to walk, along with a member of the study staff. For your safety, it will not be possible for you to drive yourself home or for you to have a friend or family member pick you up.

The whole lab session is expected to last about 5-6 hours, and you will receive $15/hour.

Field Test:

After Lab Session 1 or when you come to the lab to pick up the device, you will be instructed to wear the Skyn monitor for a 2-week period. We will show you how to use the mEMA app, Skyn monitor and its app. The research assistant will help you download the EMA app on your smartphone, enter an 8-digit unique ID code for you and show you how to enter a drinking session and answer the prompted questions. The RA will also help download the Skyn app and show you how to pair the app with the monitor. Instructions and demonstration of how to charge and operate the Skyn monitor will also be given. Procedures for the two-week field test will be explained. You will have time to practice with the apps and monitor until you feel efficient with all. You can take it off for shower or bath, swimming, charging the device, or when your activities may cause damage to the monitor (e.g., exposure in the rain, heave labor). We will ask you to check the battery status once every other day and charge it if needed.

The Skyn monitor must be returned to us intact at the end of this period, otherwise the cost of the device ($100) will be deducted from your participant payment. Before the two-week field use period, you will be asked to sign a statement that you agree to this payment reduction should the Skyn monitor be lost or damaged.

By initialing, I indicate my willingness to abide by this condition: _____

Since the Skyn app is only compatible with iOS, if you do not own an iPhone, we will lend you one for the duration of the field test. This iPhone is to be used for research purposes only. Any personal use is not allowed except reaching out to us via phone call or text about the study (e.g., you need help with the Skyn device). The iPhone must be returned to us intact at the end of this period, otherwise $200 will be

deducted from your participant payment. Before the two-week field use period, you will be asked to sign a statement that you agree to this payment reduction should the iPhone be lost or damaged.

By initialing, I indicate my willingness to abide by this condition: _____

If only doing the field test portion, at the end of the two-week period the RA will schedule a time for you to come to the lab to drop off the study devices. At this visit, you will also be asked to complete a survey on the acceptability and usability of Skyn and its app as well as the TLFB. You will receive payment for the two-week period after all these components have been completed. If you are unable to return to the lab for any reason, we will conduct the usability/acceptability survey and the TLFB remotely (by phone or online). You will also have the option of mailing the study devices back to the lab. If mailing the devices, the study team will send a prepaid box or envelope to your preferred address.

EMA:

You will be instructed to enter information on each drinking session using an EMA app called mEMA (ilumivu, Inc.). Please initiate an on-demand survey in the app whenever they start a drinking episode. This survey includes questions regarding the drinking episode such as the starting and ending times of each drink, types of drinks, drinking amount, and food intake. To capture any potentially missed self-initiated entry at the time of drinking, the EMA app will also prompt questions at a fixed schedule every morning to ask about alcohol consumption in the past 24 hours. The morning prompts will also include reminders to check the battery life of the monitor and to upload EMA data, and report issues they had with the Skyn monitor. We will contact you via phone call if we notice any issues (e.g., missing daily prompt, reported monitor malfunction) so that these issues can be resolved in time. You will receive $70 ($5/day) and another $70 if you complete ≥80% of the EMA questions, wear the monitor ≥80% of the time, and return it to the lab.

Lab Session 2:

If asked to complete all components of the study, after completing the two-week field test, participants will return to the lab for a second drinking session. The procedures will be the same as in Lab Session 1 with only one exception: Instead of training/practice with the monitor and app, you will be asked to complete a survey on the acceptability and usability of Skyn and its app after completing the alcohol-drinking portion of the session. Before dismissal, the RA will help uninstall the apps on your phone.

Participant Obligations

Participation in other studies:

While you are actively participating in this study, please do not enroll in any other studies without first letting us know and informing us of the details of this other study. Some studies conflict with one another as to what they ask participants to do. For that reason, it may not be possible for you to do this study and another study at the same

time. In that case, it will be up to you to decide which study you would like to take part in first.

Honesty and arrival at all sessions:

We rely on our participants to give us honest and accurate information on all study interviews and on all questionnaires, so please answer all of these as completely and honestly as possible. While it is normal for life circumstances to make it challenging to keep scheduled appointments, please try to arrive as scheduled for all study appointments or to let us know by email or phone if you will not be able to attend or if you will be late.

Drug/alcohol use and safety:

Please avoid using illegal drugs while participating in this study and please comply with our request to refrain from drinking alcohol on the day of each session. Following the end of the period of alcohol consumption during the session, we will ask that you remain in the research facility until your breath alcohol reaches the safe level of 0.00%. You will then be transported directly home by a professional transportation service or an automobile owned by the University of Florida, driven by study personnel.

The requirement that you remain at the research facility until your breath alcohol level declines to a safe level is to protect your safety and the safety of other participants, so we ask that you please abide by these rules.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

We expect you to be in the study for about 3 months.

9. How many people are expected to take part in this research study?

A total of up to 160 participants are expected to participate in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Breach of confidentiality:

Our study will collect data on alcohol use from persons living with HIV. HIV infection is a very sensitive health condition. Breach of confidentiality could occur via communications with participants, loss of research data, and transfer of data. Precautions are taken to ensure that all research materials are inaccessible to anyone other than the investigators. Whenever possible, research participants will be referred to by study-assigned ID numbers rather than by their name or other personal information. Accordingly, results of interviews and questionnaires, breath alcohol concentration, and urine drug/pregnancy screening are recorded by staff members on paper forms using study IDs only.

Some private identifiable information about individuals will be collected to enroll and contact participants. This information will be collected primarily via paper forms, which will be stored in locked filing cabinets at the research facility and only be accessible by study staff and other authorized individuals (e.g., members of the University of Florida Institutional Review Board). This includes a master list connecting participant study identification numbers to participant names.

Research data will be entered and stored on a secure server at the University of Florida, with no identifying information. Lab data (including monitor readings, breathalyzer readings, and information related to drinking such as timing and number of beer) and field data (including monitor readings and self-reports using EMA) will be linked using study ID. None of the study documents or communications with participants will directly identify the study as related to HIV. No data in the research data base will have participant's PHI. No results will be published in a personally identifiable manner.

Alcohol consumption:

A number of medical conditions could potentially be worsened by acute alcohol consumption (e.g., liver disease, cardiac abnormality, pancreatitis, diabetes, neurological problems, and gastrointestinal disorders). If you have any of these medical problems, you should not participate in this study. Alcohol may also cause nausea in high doses; however, nausea is not expected at the doses being used in this study. Although it is unlikely that you should experience noticeable difficulty with your motor coordination as a result of consuming alcohol in this study, you will be closely monitored by study staff during the alcohol drinking session to avoid possible accidents such as falls. For your safety, we will require that you remain in the research facility where the alcohol drinking session takes place until your breath

alcohol reaches the safe level of 0.00%. You will be transported directly home after your breath alcohol reaches 0.00%.

Breath screening, urine tests and HIV oral swabs testing:

Breath screening and urine collections are performed primarily as safeguards and should add no risks other than those normally associated with these procedures. Both tests will be conducted in house and the urine sample will be disposed after testing is complete.

To determine which group (HIV+ or HIV- as comparison) you should be assigned to, we may perform an oral swab to test for the antibody to HIV. An antibody is a substance that blood cells make to fight infection. A positive HIV test means that your sample tested positive for HIV and that repeat testing will be performed to confirm (prove) this finding. If your sample is proved to be positive for HIV, it means that you are a carrier of HIV and that you can pass the virus to others by intimate sexual contact, by sharing needles, and through donating blood and organs. A negative HIV test means that no antibody to HIV was found in your blood sample based on the result of the initial screening test, repeat screening tests, or a confirmatory test.

There can be individuals who have HIV test results that are called “false positive,” i.e., for some reason, the test indicates that HIV antibodies are present in the blood when they are not. There can also be false negative results which can have two possible meanings; the person has been infected with HIV, but that person’s body has not yet made antibodies to the virus, or HIV antibody is present in the person’s blood, but for some reason the test failed to detect it.

If you tested positive in the oral HIV test, we will refer you to the Alachua County Department of Health for a confirmatory test.

When your test results are complete, you will be scheduled for an appointment to discuss your HIV results. If you test positive for HIV, the DOH will do the following:

- Confirm the result by sending a sample of your blood for another HIV test.
- Provide information on medical and support services available to you; and
- Discuss information on the importance of notifying previous and current sexual partners that they may have been exposed to HIV and how to prevent HIV transmission.

Risks

Testing positive for human viruses (HIV) can be upsetting. You will be provided with information on medical and support services that may be available to you. If you test positive for HIV and that information were to become public, you could have problems getting insurance or a job.

Confidentiality

Your identity and test results will be kept confidential to the extent permitted by Florida Law. If test results are released in accordance with Florida Law, this disclosure will

be accompanied by the following statement: "This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for this purpose."

Questionnaires and interviews:

The questionnaires you will complete and the interviews that you will take part in for this study concern topics such as mood, drug and alcohol use. While these questions are not usually considered invasive, some of these questions require personal information. You are free to refuse to answer any question, although this may affect your eligibility for the study, should you refuse to answer questions that are part of the screening process.

Alcohol monitoring using wrist and ankle monitor:

The wristband monitor itself is noninvasive and adjustable for different wrist sizes. It's very unlikely to cause any discomfort based on our experience. The risk for breach of confidentiality associated with the monitor is very low. Similarly, the ankle monitor is noninvasive and adjustable for different ankle sizes. Thus, it is very unlikely to cause any discomfort based on our experience. The risk for breach of confidentiality associated with the ankle monitor is also very low. The data will be stored in the monitor's data porter and will be downloaded to secure UF drives after each lab session and the field test. Only study ID will be used to link the data.

Ecological momentary assessment (EMA) of self-reported drinking:

The EMA involves minimal risk as it only collects self-reported drinking data and issues related to the monitor. The possibility of confidentiality breach is very low, because the data collected from the mobile app will be encrypted and pushed to the cloud-based storage database. Additionally, the App will need the study ID to collect data, with no requirement of other personal information (e.g., phone number).

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

There are no direct benefits to you as a participant, although some persons enjoy participating in studies that can provide information to help others. A continuous self-monitoring of alcohol consumption using the wrist worn alcohol monitor may increase your awareness of your drinking behaviors and patterns, but may not necessarily change your drinking behaviors.

11b. How could others possibly benefit from this study?

Should you choose to participate, others could possibly benefit from the information you provide us regarding how accurate the alcohol monitor is and whether it can be a useful tool for changing unhealthy drinking behaviors.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

There are no other conflicts of interests.

12. What other choices do you have if you do not want to be in this study?

Should you choose not to participate in this study, we can give you information about other research studies for which you may be eligible. If your reason for not participating has to do with interest in changing your drinking behavior, we can recommend programs that may help you to reduce your drinking.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- Adverse reactions to alcohol consumption in the course of the study
- Any medical conditions that contra-indicate the consumption of alcohol that come to light after your participation in the study has begun.
- Study staff verify instances when you have not been entirely truthful with the information you provide to us
- Not arriving for appointments for the study as scheduled
- Non-adherence to study procedures
- Other administrative reasons

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There is no cost to you for participating in this research study.

15. Will you be paid for taking part in this study?

Compensation for the study is up to $410 in gift cards if you complete all components.

Payment for the screening appointment will be $10-$20 in gift cards provided that your urine test does not indicate use of any of the drugs listed above and provided that your breath alcohol level does not lead to the appointment needing to be rescheduled (Not applicable to field test only participants). The payment you earn for the screening appointment will be yours to keep even if you decide not to continue in the study and even if you are excluded for participating for reasons other than urine drug test or breath alcohol results. For the field test only participants, if the screening is done remotely, you will receive $10 as compensation for using your phone minutes and $10 for completing the first set of questionnaires. You will then receive $10 for coming in to pick up the skyn device and completing the second half of the in-person screen plus an extra $10 if you keep your originally scheduled appointment. If asked, you will receive $20 for bringing in your medical records containing your most recent HIV lab values (CD4/Viral load). Payment for completing each alcohol drinking session is $15/hour in gift cards. As mentioned before, the drinking session pays up

to $90. Payment for completing the field test (including wearing the monitor, recording drinking episodes and answering questions in the EMA app) will be $70; and you will get another $70 if you complete ≥80% of the EMA questions, wear the monitor ≥80% of the time, and return it to the lab. Should you end your participation at any point before concluding the study, you will be compensated on a prorated basis for all portions of the study you have completed up to that point. Additionally, you will also receive an extra $10 for each appointment that you attend and do NOT reschedule (IPS, drinking session 1, and drinking session 2) (Not applicable to field test only participant). Also, if you show up at the in person screening appointment, but we have to reschedule the appointment due to reason on our end (e.g., logistic issues), we will still pay you $20 for this appointment to compensate your time/effort.

You can choose to receive an eGiftcard or a gift card mailed to you in the mail, if you prefer not to pick up a gift card in person.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html

Your payment for participation in this research study is by gift cards handled through the University of Florida's Human Subject Payment (HSP) Program. Your information, which will include your name, address, and date of birth is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the Principal Investigator.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Name
- Contact Information
- Date of Birth
- Social Security Number (For compensation purposes)
- Research study records
- Records about phone calls, email and text message communication made as part of this research
- Records about your study visits
- Results of urine drug screens, HIV test, and pregnancy test
- Responses regarding your health provided on questionnaires and in response to interviews
- Information regarding the use of illegal drugs

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information

that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine your eligibility for the study
- To investigate whether the Skyn monitor works the same for HIV+ and HIV- individuals as well as for different genders.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .

- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of this study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date