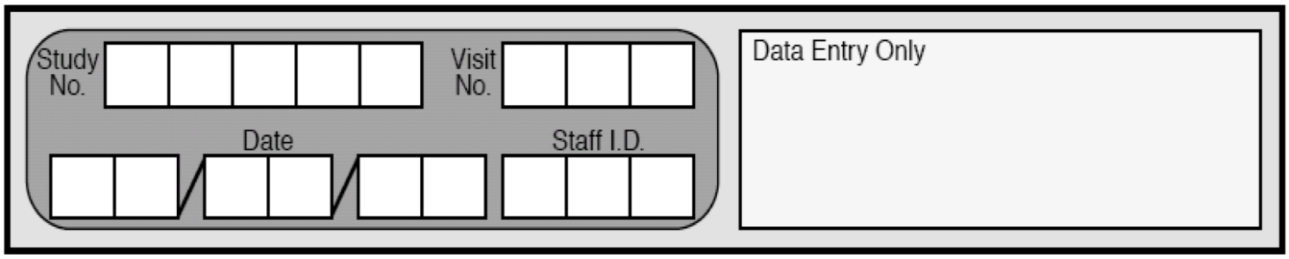

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University of California, San Diego
Consent to Act as a Research Subject

REAL-TIME MOBILE ASSESSMENT OF DAILY FUNCTIONING AMONG OLDER HIV+ PERSONS [Full Evaluation]

Raeanne C. Moore, Ph.D. and her associates at the HNRP are conducting a research study to examine the usefulness of ecological momentary assessment (EMA) via smartphones to measure daily functioning among older adults with HIV. EMA is a mobile data collection technique in which surveys are completed several times a day on a smartphone provided by us. You have been asked to participate because you are HIV-infected or uninfected with HIV and are 50 years of age or older. The purpose of this study is to determine whether smartphones can help us better understand real-world daily functioning behaviors. There will be up to 200 participants in this study. This study is being funded by the National Institutes of Mental Health (NIMH).

If you agree to be in this study, the following will happen:

1. You will first meet with a project staff member to undergo approximately 6-8 hours for the Baseline Assessment at the HNRP. During this assessment you will complete neuromedical, neuropsychological, and psychiatric evaluations.

1a. Neuromedical Evaluation: We will perform a general physical examination of how well your brain and nervous system are functioning (this exam consists of questions and an evaluation of your reflexes, strength, hearing, touch and other senses). If you are currently taking any medications or supplements for the treatment of HIV, you will be asked to bring these with you to your evaluation. This portion will take about 1.5 hour to complete.

1b. Blood Draw: You will be asked to undergo a blood draw. Approximately 10 tablespoons will be drawn and used for medical tests. This will take approximately 20 minutes. These blood samples are used for research and are not a part of any clinical care. The blood tests done will be used for research and are not a part of your clinical care. Analysis of fluids done for this study may indicate if you have infections other than HIV. If our analysis shows that you have an infection that you have not reported (e.g. syphilis), you will be notified in a face-to-face meeting with study personnel as soon as possible and this information will be documented in your research record. If needed, you will be provided with a referral to a medical professional for further assessment and/or treatment.

These samples will be stored for possible future testing and may also be used to isolate your DNA (the genetic material inside your cells). Fluid samples and data collected in the course of the study are banked and may be sent to other research scientists anonymously (without identification). If the blood draw is unsuccessful or the sample obtained is unusable or less than needed to complete the tests, you may be asked to return for a separate visit to complete another blood draw. If you are asked to return and come in for the procedure, you will receive additional compensation for that visit as described in the compensation section below.

1b. Neuropsychological and Psychiatric Evaluation: You will be asked to perform some tasks (also called neuropsychological tests), which will measure your memory, concentration, reasoning, quickness, and alertness. Some of these tasks will require you to use paper and pencil or computer keyboard. You will also be asked to complete brief demographic questionnaire, questionnaires about your general medical conditions, emotional history, health behaviors, lifestyle, social, physical and mental activities, general outlook on life, and your comfort with computers and mobile technology, and tests of your memory and cognitive abilities. These tasks will take approximately 6 to 8 hours to complete.

1c. Because some of the medical tests and interviews may be affected by recent drug or alcohol use (for example, tests of memory and quickness) you will be asked to blow into a breathalyzer and give a urine sample to measure these substances on each day you participate. If results of these tests show that you may have recently used one of these substances, you may be asked to reschedule your assessment for that day.

2. At the baseline assessment you will be given a smartphone to carry with you for two weeks. The device will be programmed to alert you to complete a questionnaire at five random times each day for the two-week period. Each questionnaire is limited to approximately 5-10 minutes, and the electronic interviews will ask questions about where you are, who you are with, what you are doing, the experience of stressful events, and your feelings. Additionally, you will be asked to perform brief cognitive assessments on the smartphone upon completion of some of the surveys. You will receive a 30- to 45-minute training session on how to operate the smartphone, the meaning of all questions and response choices, and procedures for carrying the device and responding to alarms. The smartphone contains a location detecting device called a Global Positioning System (GPS) which records where you travel and tells us more about where and how you spend your days. You will be asked to keep the smartphone with you at all times from when you get out of bed to when you go to sleep.

Do not respond to survey while driving, riding a bicycle, operating machinery, or any other time that is unsafe. Study staff will teach you how to turn off the smartphone when you will be driving a vehicle or engaging in any activity where an alert may distract you or threaten your safety. Turn off the smartphone if you will be driving a motroized (e.g., car, motorcycle) or non-motorized (e.g., bicycle) vehicle. The smartphone will also have a feature called DriveMode enabled. DriveMode helps drivers avoid distractions from incoming calls and text message alerts. Enabling DriveMode turns text and calling features off when you are traveling over 15 MPH. If you forget to turn off the smartphone while you are driving, and regardless of how fast you are driving, do not respond to surveys when driving or any other time that is unsafe.

3. At the baseline assessment you will also be given an activity tracker to wear on your non-dominant wrist. You will wear this device for the same 2-week period you will be responding to the surveys on the smartphone. The activity tracker will measure your movements throughout the day and is a band that will be worn on the wrist. This device measures your

physical activity via accelerometry (i.e., step counts per day). It also has sensors that assess your sleep quality. For this study, we will examine the relationships between your physical activity, sedentary behavior (i.e., time when you are not physical active), and sleep quality and your real-world daily functioning behaviors. The activity tracker is about the size of a wrist watch. You will wear the activity tracker for waking **and** sleeping hours, except when you are bathing or swimming. This device should not be considered a medical device or significant risk device.

4. Upon completion of the 2-week period, you will be asked to return to the HNRP to 1) return the smartphone and activity tracker, and 2) complete a follow-up interview, which will include questionnaires about your recent mood, daily activities, and your experience using the smartphone and taking the electronic questionnaires.

In terms of total time commitment, the baseline interview and smartphone training will last about 7 to 9 hours and the follow-up interview will last about 1.5 hours. You will be asked to complete 2-weeks of questionnaires on the smartphone. Each questionnaire will take approximately 5-10 minutes to complete.

PARTICIPATION IN OTHER STUDIES

By signing this consent, you understand and agree that data collected in this study (e.g., cognitive test results, questionnaires, and lab results) may be available to HNRP investigators conducting other IRB approved research. This information may be used for analysis and to determine if you are eligible for other related studies that Dr. Moore or her associates at the HNRP are conducting. If you are eligible, you may be informed about these studies. Whether or not you choose to become involved in those studies will not affect your continued involvement in this study. If you decide to enroll in other studies, you will sign a separate consent form. Note that if you choose to participate in other studies conducted by Dr. Moore or her associates, data collected during those assessments or procedures may be shared with this study. **In this case, you will be compensated only once for each procedure you complete on any given day.** Additional procedures requiring separate visits may involve additional compensation.

☐ YES, you would like to be considered for other studies.

☐ NO, you do not want to be considered for other studies.

METHODS FOR CONTACTING AND LOCATING YOU

You will be asked to provide information that will help us locate you in the future to follow-up up with you about this study or inquire about your interest in other studies. This information may include your contact information and information about others who might be able to locate you in the future. You can choose which information to provide. We will use the information provided by you as well as publicly available methods (e.g. internet search) to locate you as needed. All contact information we collect will remain confidential.

COMPENSATION

You will receive compensation at each visit based on the following schedule:

If you complete the entire your first visit $105

If you complete a portion of the visit, you will receive compensation based on the following schedule:

If you complete the medical assessment (blood draw, medical examination and Interview, completion of forms)..... $40

If you complete the neuropsychological assessment (neuropsychological testing, interviews, history, completion of forms and urine sample) $35

If you complete additional assessments (additional neuropsychological tests, questionnaires) and smartphone training $30

Second visit:

If you complete the follow-up assessment $15

If you return the smartphone and activity tracker..... $25

If you are asked to return for a separate visit to complete a blood draw..... $20

Additionally, you will be paid $1 for each at-home survey you complete on the smartphone, with an option of $1/survey x 56 surveys = $56.

If you begin but do not complete the medical exam or the neuropsychological testing (including the urine sample), you will receive a payment of $10 for that procedure. If you begin but do not complete the blood draw for any reason, you will receive full compensation for the procedure.

There is no cost to you for participation in this study.

RISKS AND DISCOMFORTS

If you take part in this study, you may have some added risks or discomforts. These include:

1. You may experience discomfort or a sense of loss of privacy as a result of revealing your location and daily activities or answering survey questions. The GPS feature on the smartphone collects data on where you are at all times, just like information collected by non-research smartphones. This data is not transmitted or viewed in real time. There is a small risk of loss of confidentiality.
2. You may feel uncomfortable while wearing the study activity tracker, though there are no known health risks associated with wearing these devices.
3. Pain, bruising, fainting, swelling, dizziness or possible infection at the blood withdrawal sites.

4. There is a risk you may test seropositive for HIV infection if you currently believe you are seronegative.
5. Despite every possible safeguard, there exists the slight risk that confidential information regarding your history, substance use or health diagnosis and DNA information (genetic risk of certain diseases) may become known outside of the research setting. Although such an event is unlikely, it could be potentially damaging to your insurability and/or employability.

   Federal and State laws generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: a) Health insurance companies and group health plans may not request your genetic information that we get from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that these laws do not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

BENEFITS

You will not receive any direct benefit from participating in this study. The new knowledge gained may help others in the future.

UNFORESEEABLE RISKS

Participation in this research study may involve risks that are currently unforeseeable. However, if any new risks become known while you are participating in the study you will be informed of them.

NEW FINDINGS

You will be told of any new, relevant information that comes out while you are in this study that might lead you to change your mind about staying in the study.

GENETIC INFORMATION

DNA, the genetic information inside your cells, is part of the blood collected in this study. Your DNA, or the information from it, will be kept

indefinitely, and may be used for additional research in future studies. Dr. Moore, her co-investigators and successors at the University of California will be responsible for deciding how your DNA and/or the information from it will be used. The samples may be shared and used for future research with research scientists at UCSD as well as with research scientists outside the University. This DNA and/or information may have significant therapeutic or commercial value. You consent to such uses.

Participation in these studies does not mean that you have had genetic testing. Genetic testing means having a test performed and the results provided to you and your doctor. If you are interested in having genetic testing performed you should consult your doctor. There will be no direct benefit to you from these tests, since you will not be provided with results or information regarding any genetic testing that might be performed. The investigator, however, may learn more about genetic factors that contribute to diseases of the nervous system caused by HIV.

If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Moore, who will use her best efforts to stop any additional studies. However, in some cases it may be impossible to locate and stop such future research once the materials have been widely shared with other researchers.

ALTERNATIVES TO PARTICIPATION

The alternative to participating in this study is to choose not to participate.

WITHDRAWAL/REMOVAL FROM THE STUDY

Participation in this research study is entirely voluntary. You may refuse or withdraw participation in this study at any time without affecting your medical care at this institution or loss of benefits to which you are otherwise entitled. Likewise, your participation may be discontinued without your consent, if you fail to comply with the study procedures, if the study is cancelled by the investigators or the sponsor, the HNRP, or if, in the investigator's clinical judgment, discontinuance is in your best interest.

If you wish to withdraw, please notify Dr. Moore or an HNRP staff member by calling 619-543-5000. If you decide to withdraw from the study or are withdrawn by the investigators, you will be asked to come to the HNRP to return the smartphone and activity tracker and you will be compensated $25 for doing so.

CONFIDENTIALITY

We will do everything we can to keep others from learning about your participation in the research. Despite careful safeguards, information regarding your history, DNA information (genetic risk for certain diseases), drug and/or alcohol use, or medical diagnosis may become known outside of the research setting. Although such an event is very unlikely, accidental disclosure of your history or medical information could be potentially damaging to your insurability, employability, and/or ability to travel. To further help us protect your

privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS and the UCSD Human Research Protections Program for the purpose of audit or evaluation.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer, employer or other outside party, learns about your participation, and obtains your or your legal guardian's consent to receive research information, then Dr. Moore and his associates may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Dr. Moore and her associates are not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. If Dr. Moore or her associates determines reporting to authorities is necessary because of imminent serious danger to yourself or others, then they would only disclose information in your records to the extent necessary to prevent such imminent danger.

Information from this study is available only to study investigators, authorized personnel, and the UCSD Institutional Review Board. To guard your privacy, only a special code number will appear on questionnaires, and all records, forms, and information will be kept in locked file rooms and cabinets. Each sample is labeled with a unique non-identifiable study ID. All stored samples are accessible only to the HNRP laboratory personnel and the appropriate study members. Samples are stored under the coded identifiers in freezers equipped with locks in a location that requires ID scan entry.

The smartphone is password protected. No personally identifying information will be stored on the phone and the phones will be locked-down, meaning you will be unable to input personal telephone numbers or other personal information into the phone. In other words, the device will not have access to photos or other personal inputs. Since we will be providing the devices to you, there is no risk of loss of confidentiality associated with access to personal telephone numbers. Should you lose the device, we will take the additional step of incorporating the Autowipe application on all study devices which enables remote factory reset of the device, erasing all data. Should you lose the device you will not be held responsible for the cost of the device or any other costs.

No personally identifying information will be stored on the activity tracker. Since we will be providing the activity tracker to you, there is no risk of loss of confidentially associated with access to your daily activity data. Should you lose the activity tracker you will not be held responsible for the cost of the activity tracker or any other costs.

CONSENT

Dr. Moore and/or _____ has explained the study to you and answered your questions. If you have other questions, or wish to report a research-related problem, you may call Dr. Moore or her associates at (619) 543-5000. Please note: This number will only be staffed during business hours (M-F, 8:00 AM – 5:00 PM). You have received a copy of this consent document to keep and the "Experimental Subject's Bill of Rights."

You agree to participate.

_____

Subject's Name (Printed)

_____ _____

Subject's Signature Date