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Consent to Participate in a Research Study

MOODS Study: Mobile Open Observation of Daily Stressors

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study. This research is designed to answer several key research questions in computer and clinical science. If you volunteer to take part in this study, you will be one of about 100 people to do so in this phase. This research may result in future phases that continue to advance our understanding of key scientific domains. The box below highlights key information for you to consider when deciding if you want to participate. More detailed information is provided below the box. You are welcome, and encouraged, to ask any questions about the study before you make your decision.

Key Information for You to Consider
Voluntary Consent: You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefit to which you are otherwise entitled if you choose not to participate or discontinue participation. **Purpose:** The purpose of this research is to help advance mobile health (mHealth) platforms. We want to advance mHealth platforms by answering questions about stress and stressors. In doing so, we can answer several technical questions that will help several scientific fields. **Duration:** It is expected that your participation will last 100 days, but you can participate longer if you choose. **Procedures and Activities:** You will be asked to wear a wrist sensor ("smartwatch"), that we provide you, for 100 days. You will be asked to download special study software on your smartphone to collect the wrist sensor data and to reflect on your day, every day. You will use a computer login to review your data and provide feedback about how to make the systems better. After the study is over, we will release the dataset publicly. We will provide a period of time for you to censor data that you do not want released to the public. **Risk:** The most important risk of this study could be to your privacy. We will take steps to preserve your privacy, but we are releasing data that do not directly identify you to the public after the study is over. If you link your identity (like from other studies where you've given personal information that is open to the public), then people will know information about you that was collected from this study. This includes the inference (i.e., identification via computer code) of behaviors. Future computer code could automatically identify behaviors from your dataset. If you link your identity to this dataset, people could learn things about you that you may not foresee possible in the future. No personal benefits to you are guaranteed from participating in this study. However, your participation will advance mHealth science in several scientific fields. **Alternatives:** Your participation in this study is voluntary, and the only alternative is to not participate. If you don't participate, your decision will not affect your participation or ability to participate in other studies or receive other benefits that are unrelated to this study.

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WHO IS DOING THE STUDY?

This study is being conducted by the Center of Excellence for Mobile Sensor Data-to-Knowledge (MD2K Center) at the University of Memphis. The study coordinator is Mr. Shahin Samiei, and he can be contacted at moods@md2k.org. The Principal Investigator of this study is Dr. Santosh Kumar. You are invited to ask us questions about this study or your participation at any time. To ensure that we respond to all questions and feedback, please direct all communications about the study via email, at moods@md2k.org.

WHAT IS THE PURPOSE OF THIS STUDY?

This study has three primary research questions to advance mobile health (mHealth) platforms:

First, we want to study how computational models (advanced computer code) can detect, distinguish, and/or predict stressors among living people. Stressors are defined as precipitants, or things that happen before people become stressed.

Second, we want to study how patterns of stress take place within individual people from day-to-day, and how patterns of stress take place between different people. This information can help in future research that can tailor interventions that can reduce stress and improve health.

Finally, we want to explore the different structures and functions of the data we collect from this study. All data (information) that is collected in our society has metadata (data about the data) that is very important in contextualizing the data. We are trying to build and test what metadata is most useful for mHealth research, especially regarding privacy and when data are missing.

We hope that asking a group of highly engaged citizen scientists will help us learn more about these research questions. Ultimately, this information will help us to plan future studies that look at how mHealth technologies can improve health.

We (the research team) will be using your feedback throughout this study to help guide our research questions, and any other questions that arise during the study. **We plan to generate a publicly released (i.e., open) dataset that uses your data and the data from others in this study.** We will post this dataset on the internet for anyone to download. This will only happen after you have a chance to review and consent on what we are collecting (as explained in this consent form), and after you have a chance to review and censor what information can be shared. We are doing this because the richness of the dataset that we are collecting will help future researchers perform additional research.

WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH? ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

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1. We are recruiting healthy adult individuals from the United States between the ages of 18-64 years (19-64 years if Alabama or Nebraska resident, or 21-64 years if Mississippi resident)
2. We are recruiting individuals willing to wear a wrist sensor for all waking hours (i.e., at least 12-16 hours per day, except when charging, bathing, or swimming) during the 100-day study period.
3. We are recruiting individuals with a smartphone compatible with the data collection application suite and adequate data connection (Wi-Fi access or sufficient cellular data plan) for communication with University of Memphis servers.
4. We are recruiting individuals who experience daily stressors.
5. We are recruiting individuals who intend to maintain participation and active consent in the Open Humans or Personal Genomes Project, if applicable.
6. We are recruiting individuals who identify as citizen scientists, or who otherwise have an interest in the “quantified self” or other self-monitoring groups.
7. We are recruiting individuals who are capable of providing their own consent and understanding the study procedures in English
8. We are not recruiting individuals residing outside of the United States or who intend to move outside of the United States during the 100-day study period.

If, for any reason, you feel uncomfortable with the study procedures, you should not take part in this study. If you decline to take part in this study, it will not be held against you.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted remotely, using your own smartphone and computer. The research activities and data collection will be centralized at the University of Memphis. Participants are asked to take part in the research procedures for at least 100 days.

Participants are not required but may continue to contribute data as long as they want. Eventually, following the end of data collection from the 100 planned participant completers, the data collection platform will likely be taken offline. This means that you may still collect data on yourself, but you will not be able to connect to the back-end server, and the overall study platform functionality will be reduced.

WHAT WILL YOU BE ASKED TO DO?

1. If you agree to be in this study, we will provide you with a wrist-worn sensor (smart watch) via certified mail or an equivalent shipping method. We will provide you instructions for downloading a mobile software suite for data collection from the sensor and your smartphone.
2. Once daily for 100 days, you will be asked to complete a survey that asks you to reflect on potentially stressful periods in your day (identified by the sensor and study software). Every week, we will also send you short surveys to reflect on your (1) awareness of stress over the past week, your interactions with the stress visualizations, and (3) the burden of completing

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study procedures. The stress awareness questionnaires will only be sent to you for the first 5 weeks. The other assessments will be sent to you every week. You will also be asked to complete several baseline surveys via your computer or smartphone at the beginning of the study.

3. When you begin the study, you will be asked to log into the system with your email address. You will use this login to access an online system to review your data. You will be able to see graphs and other representations of the data. You will be able to see your data and the data from other people in this study that is not individually identifiable. They will be able to see data from you that does not identify you. You may use this system to provide feedback of what representations are useful, and how they could be made better.
4. You can also use this online system to censor your data. In other words, you can pick what data you do not want shared publicly when the study is over. The study team can still use the data to answer the research questions, but we will not share it with anyone else if you mark it as censored. After your 100-day data collection period has ended, you will have at least an additional 30 days to ensure your data are censored before public release. We will inform you when the 100 days has passed.
5. To further elicit feedback from participants like you in this study, we will invite you to join a private (closed to the public) online discussion forum on a website like reddit.com. We will ask that you create an anonymous account (using a pseudonym) to join the group. Here, we will post aggregated analyses and visualizations to elicit feedback. You can also comment on your participation in the study and ask questions from other participants like you.
    a. We will not share any identifiable or personal information in this group, though be aware that if you self-identify yourself, there may be unforeseen privacy risks to you.
    b. Your participation in this forum is optional and does not affect your participation in any other component of this study.
    c. After the study is over, we may publicly share de-identified data from this forum like your feedback or comments to help us continue to evaluate this study and for further research utility.
6. If you do not want the sensor or smartphone software to collect information about you at all, we will provide instructions how to temporarily pause the phone and sensor from collecting data. This will mean no one can see the data, including you, the research team, or the public.
7. We understand that it may not be practical to wear the sensor and/or smartphone device all the time. When you cannot wear them or you do not want to wear them, you may take them off.
8. You will need to charge the wrist sensor and the smartphone every night. We will provide a charging cable for the wrist sensor that you may keep.
9. During the study, the wrist sensor will be collecting data about your physical movement and heart rate. This information will be collected from the wrist sensor onto the study smartphone, via the software we provide.
10. This information by itself won't be able to identify you individually, but we will be able to use this information about your heart and wrist movements to determine certain behaviors and health states: For example, we will be able to know if you are stressed, smoking, or eating. In the future, the information collected from this sensor may be able to discern other, yet unknown, behaviors.

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11. The smartphone software will also be collecting non-identifiable information from the internal smartphone sensors. This could include whether the phone is moving, whether the phone is active (screen on/off), and interaction/communication events with the phone. These events would be aggregate counts (like number of calls, duration of calls, number of text messages), but would never include content or identity (name or phone number) of communications.
12. During the study, the smartphone software will be collecting your location (where you are) via GPS. This information will be used to determine the context of your stress episodes. Only authorized members of the research team will see your GPS data for research purposes. **We will not share the raw GPS data (your exact location) when we release the public dataset**.
13. We will code your GPS into "semantic locations", also known as "clusters" or "points of interest/POI" – these are de-identified codes of places that you have been. Rather than using raw GPS that can identify individual addresses, our codes might say "home", "work", "school", "in car", or other location codes. We will share this coded information publicly in the public dataset.
14. The phone will send all collected study data to a secure computer periodically throughout the day via Wi-Fi or a cellular connection. We will use a secure method of transmitting your data (HTTPS), similarly to how your phone would communicate with your bank or a secure cloud storage app that you may use on your phone.
15. We ask you to participate for at least 100 days. This means wearing the wrist sensor for all waking hours (i.e., at least 12-16 hours) every day, and respond to the survey prompts. This will help us get enough stress episodes and stressor events to be scientifically helpful. However, you are allowed to end your participation at any time, for any reason. We ask you to inform us if you decide to end participation early.
16. After 100 days, you can keep participating or end your participation. After 100 days, we ask that you have completed the following:
    a. At least 800 hours of sensor data collection.
    b. Completed the daily review of stressors at least 5 times per week.
    c. Complete at least 4 of the 5 weekly awareness questionnaires (first 5 weeks of the study).
    d. Complete at least 10 of the 14 weekly visualizations assessments.
    e. Complete at least 10 of the 14 weekly burden assessments.
17. If you do not participate in the study for seven days in a row without telling us, we will assume you have stopped participating in the study.
18. After you end participation, you can uninstall (remove) the study software from your smartphone, just as you would to remove other applications. We can provide instructions to help you do this if needed.
19. At the end of the study, you can choose to keep the wrist sensor, or you can ship it back to us via a pre-paid postage label if you do not wish to keep it. If you choose to not complete the study, we will ask that you return the wrist sensor to us.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

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- To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.
- Wearing the wrist sensor may be uncomfortable, but most people get used to them. If the discomfort is intolerable, you may remove the wrist sensor and the discomfort will go away.
- You will need to download an additional software suite to your phone that will be collecting data about you from the wrist sensor, internal phone sensors, and GPS. In the event your phone is lost or stolen during the study period, this data and all other data on your phone (photos, any sensitive apps like for banking, etc.) may be compromised. Hence, we recommend securing your phone to protect your study data in the same manner you would secure your other personal information like banking information or photos.
- You will need to charge the wrist sensor nightly or during periods of time convenient to you. We will provide a cord to reduce the burden of charging the device.
- The study application has been optimized to run on your smartphone with all of your other applications. However, the study application may drain your device's battery more quickly than you might usually expect. If you have any questions or have difficulty maintaining battery life, you may contact the study team for guidance.
- The phone will use Global Positioning System (GPS) to collect location data. This location data could identify you by showing where you are. Research staff will protect this information by restricting access only to authorized personnel. All researchers and research staff have been trained in human subjects research (research that involves living people). All researchers and research staff will agree to not use the location data to identify you as an individual. We will not make your location data available to the public.
- We will make every reasonable effort to ensure that your information is kept secure, but in the event of a data breach, your location data (all of the places you've been during the study) could be exposed. We will minimize this risk by following best practices in information security (using administrative, physical, and technical safeguards against unauthorized access.
- We will keep all of your information confidential within the limits allowed by law. However, we cannot guarantee complete secrecy. For example, we are required by law to report evidence of child abuse or neglect.
- We are recruiting from a group of highly engaged citizen scientists (either who self-identify or because of their participation in citizen science research). We are aware that you may want to share your research data, or otherwise link it to other research data collected about you. If you have identifiers (like your name, phone number, email, or others) in other datasets, you could make the research data from this study identifiable as well. **If you choose to self-identify your research data from this study, there may be unforeseen privacy risks.**

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WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, you may find this study helpful to increase your own health awareness. Your willingness to take part may help society as a whole. Researchers may learn valuable information from this study to understand how using mHealth technologies like wearable sensors and "smart" devices can detect certain behaviors, improve health, and build technical infrastructure for additional research of this type.

DO YOU HAVE TO TAKE PART IN THE STUDY?

1. Whether you choose to take part is up to you.
2. You can choose to say "no" and not take part.
3. You can agree to take part in this research and change your mind later.
4. Your decision to say "no", whether now or if you change your mind later, will not be held against you.
5. You can ask any and all questions that you want before deciding to take part.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study. If you do not take part in the study, it will not be held against you.

WHAT WILL IT COST YOU TO PARTICIPATE?

You will be responsible for any additional data costs associated with taking part in this study. We can provide instructions for modifying this study's data to only be uploaded from your phone via Wi-Fi, if you use a limited data plan. We expect data costs to be marginal for most smartphone users. However, you are welcome to ask the study team if you are unsure of the costs to you.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will be able to keep the wrist sensor for taking part in the study. This sensor is worth about $112. You will also be able to download and keep the data that is collected from you as a part of this study. You can analyze or use those data as you wish.

We understand the value that self-quantification or self-analysis has for citizen scientists. That said, we do advise that you may encounter unforeseen privacy considerations if you share your personal data with others, or if you link your participation in this study with other studies you participate in like Open Humans or PGP.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

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This research study is a part of a research collaboration that aims to develop new ways of improving health and scientific discovery by using mobile sensor technology. Because of this, we want to save your research data and share it with other researchers who study mobile health. **We also want to share the data collected from this study (including yours) with the public, for open data science.** The rest of this section describes how we will use your data and share it with other researchers.

Data security & confidentiality: We will use best practices to prevent unauthorized access to your information. For example, we will make sure that all electronic study records and data will be kept on computers that are secured with appropriate technical safeguards such as password protection and encryption. This means it will be very difficult for someone to access your information if they do not have permission. If there is a need to make paper or physical copies of your information, we will keep those physically secured using best practices. The data center where your study data will be stored is protected using administrative, physical, and technical safeguards to prevent the unauthorized access to your information.

We will protect your identity to the extent required by law. However, we cannot guarantee complete secrecy. For example, we are required by law to report evidence of child abuse or neglect. All of your records will be open to inspection by the research study staff, the IRB, other representatives of this institution, and the sponsor of this study: the U.S. Department of Health and Human Services, National Institutes of Health, and the National Science Foundation.

How we will use your data: We will link your contact information and your research data (the data collected by all of the questionnaires, study sensors, and the phone) with a code number. In order to do this, we will use your email address as a login to generate the code number. A master key that links your name, your contact information, and your code number will be maintained in a separate and secure location from your research data. We will only use your contact information for the purposes of contacting you about this research study, and future research studies if you choose. We will use your research data for scientific progress and for publication of study results.

After your participation in study is over, you will have 30 days to perform a final review to censor any data that you do not want shared. We will make a public copy of your data and share it on the internet for the wider scientific community and other citizen scientists to analyze. We will not identify you in this open data set. However, if you choose to link your study data with other data about you that is identifiable (e.g., if you've disclosed your name or another personal identifier in a different open data set), then others may be able to connect your identity with your study data. You may consider this information as private as medical records or other personal information about yourself.

During the study, the sensors will be collecting raw data about your physical movement and physiology. This information will be collected from the wearable sensor(s), onto the study

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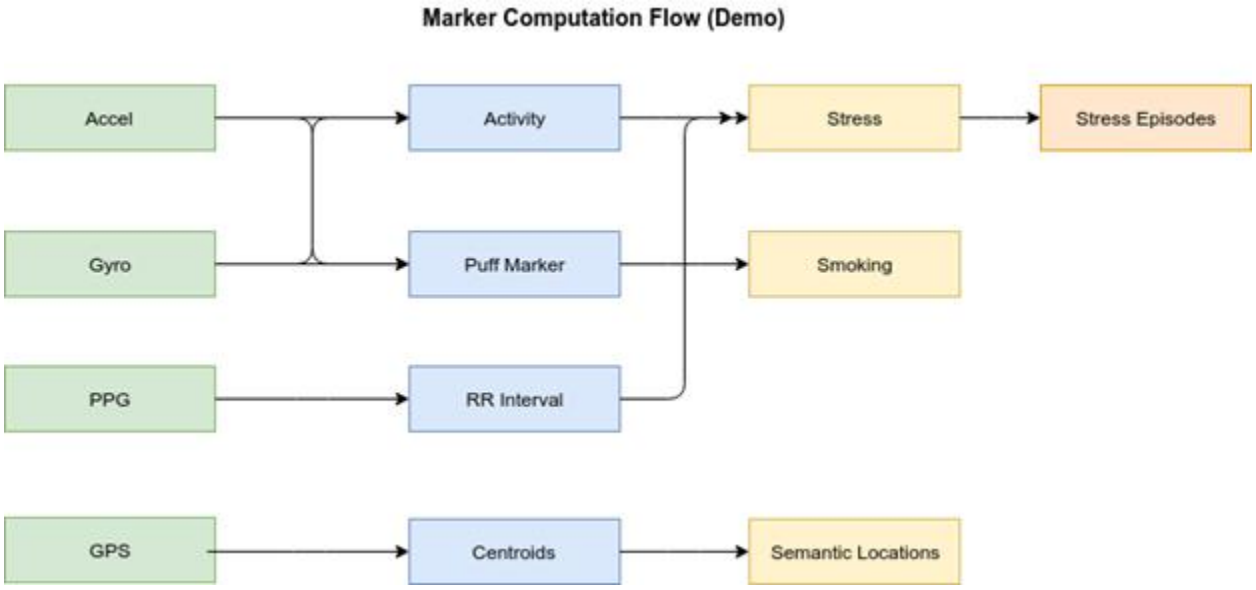
smartphone, and then on our back-end server. This information by itself won't be able to identify you individually, but we will be able to use this information about your heart rate and wrist movements to determine or infer certain behaviors and health states: For example, computer code (i.e., algorithms) may be able to infer whether you are active, stressed, smoking, or eating at specific times throughout the day. Computer code is subject to constant evolution: In the future, computer code may be able to identify other behaviors from your raw sensor data that we currently cannot identify. **If you choose to make your study data identifiable to you, there may be unforeseen privacy risks that we do not currently know about.**

- This pathway of inferring health behaviors from raw sensor data is illustrated in the following figure:



Accel: Accelerometer, a sensor in the smartwatch that detects motion
Gyro: Gyroscope, a sensor in the smartwatch that detects position of the watch in 3-dimensions
PPG: Photoplethysmography – a sensor that uses LED light to detect heart rate at the wrist
RR Interval: Interbeat interval – the time between heart beats
GPS: Global Positioning System: Uses phone-based sensor to determine latitude/longitude coordinates to detect geographic position (location) on earth.

How we will share your data: The research data that we collect about you in this study may also be shared with other researchers. Some of these researchers may be at other universities/institutions. This may include GPS data.

GPS data will contain a time-synchronized record of all of the places you have visited during the study. Because of this, GPS data could be used to identify you, and may contain locations that you consider private or sensitive. We may share data that includes your raw location data (GPS) with other researchers. However, these researchers must use your GPS data for legitimate scientific interest and under the oversight of an IRB (as with this study).

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We will share your GPS data with these other researchers only after:

1. They describe, in writing, how they will use the data.
2. They agree that they will keep your research data secure. They will agree that only people working on their study will be able to see your research data.

We will share your research data from a special database. This database will be saved on a secure computer that is operated at the University of Memphis. People who want to use this data will need permission from the person in charge of this study, Santosh Kumar. These researchers will not be allowed to share your GPS data with others, unless they agree to the same provisions and have obtained IRB oversight to work with your GPS data.

We will use your GPS data to make a code for certain points of interest (POI, also called "clusters"). These POI might say "home," work," "school," "car," or some other generic code for where you have been at a given time. We will use this code in datasets that we share publicly, so that they couldn't know your exact location while you were in the study. If you request your GPS data and then share it with anyone else, they will know everywhere that you had been during the study and could individually identify who you are.

How long we will keep your data: We expect that the data will be useful for 10 years after the study is over, but we may keep it indefinitely. After you complete your time in the study, we will we will make a copy of the data that will be stripped of your raw location data/GPS. We will save and make this copy of your research data available as long as we think it is still useful.

Canceling your permission: If you change your mind later and you don't want your research data shared with other researchers, you can cancel your permission. To cancel your permission, you have to write us an email to moods@md2k.org. When you write us an email and cancel your permission, we will delete your information from the database. No new researchers will be able to get a copy of the data. We will not be able to take back the research data from researchers who already have the data. Once we share the information on the internet, we will not be able to take back any copies that have been downloaded.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

You can leave this research study at any time and it will not be held against you. There is no penalty for deciding to leave the study now, or in the future.

If you want to leave the study at any time, contact the study team. We will arrange for the study device to be returned, if you do not wish to keep it. If you don't want your data to be used in the study, tell the study team. They will permanently delete any data that has been collected from you as a part of the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

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WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. If you have questions, concerns, complaints, or think that you've been hurt by the research, contact us as soon as possible. You can contact vis email, please email moods@md2k.org with any questions about this study.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The role of the IRB is to protect the rights and welfare of people who take part in research studies. You may contact the IRB at 901-678-2705 or irb@memphis.edu if you have any questions about your rights as a volunteer in this research. Some reasons you might want to contact the IRB are if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone who is not on the research team.
- You want to get more information or provide input about this research study.
- You have any questions about your rights as a research participant.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information regarding this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

This study is supported by a grant from the National Institutes of Health (Grant #5U54EB020404). This study is designed to research how using data from mobile sensors can be used to inform and improve health outcomes. This study is a part of collaborative research between the University of Memphis, University of California Los Angeles, University of California San Francisco, the Ohio State University, and the Pennsylvania State University.

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Your signature documents your permission to take part in this research. By signing this consent form, you agree that we can share your research data (including identifiable GPS) with other researchers who are working on this study. You also agree that we can share your de-identified research data on the internet after you have completed the study and have had a chance to review the data.

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study