

STUDY DETAILS AND PROCEDURES

As ALiR is part of UAS, the main UAS study details still apply. Below you will find additional details that are unique to participation in ALiR.

Participants: We will be asking about 1000 individuals to take part in this study.

Duration: The study period is one year starting when you download the ALiR study app and connect your provided Fitbit.

Enrollment: After consenting to this study, UAS staff will mail you a Fitbit device. Once you receive your Fitbit, we will ask you to install the ALiR and Fitbit apps on your smartphone or tablet within 1 week. The ALiR study app (as well as the enrollment guide included in the package) will help you setup your Fitbit device and account, and enroll in the study. This should take you about 10 minutes and the UAS help desk will be available to provide assistance if you need it.

Both apps that are needed for the study are free and you can remove them after the study is done. You will need to share your location information with the apps; however, we do not collect this information and it will only be used to obtain your time zone.

Once you are enrolled, we ask you to participate in two main activities for this study: (1) wearing your Fitbit on your wrist at all times; and (2) answering very short surveys on a regular basis.

Wearing your Fitbit: We ask that you wear your Fitbit on your wrist at all times, including when you are sleeping, for a whole year. You can take it off for charging, special occasions, or other reasons - just please wear it as much as possible. This means keeping your Fitbit charged and syncing with your phone or tablet as needed.

- **Charging** takes 1-2 hours and we recommend charging the device every 3-4 days. Your device will also notify you when your battery is low and needs to be charged through a push notification to your phone or tablet.
- **Syncing** should happen automatically through Bluetooth once your apps are setup.
- Your device is water resistant up to 50 m (164ft), so you can shower and swim with it on after turning on the "**water lock**" (instructions will be provided). However, this is not required, and you may take your device off to shower or swim.
- If you **lose or break your device**, please contact the UAS help desk (uashelp@usc.edu) for next steps. We will do our best to replace it.

Withdrawal: If you decide to withdraw from the study at any point, you will still receive any compensation you have earned before withdrawing. If you withdraw prior to contributing 90 days of digital data in the first 150 days, we will send you a prepaid envelope to return the device.

Payments for research participation are considered taxable income and participants may be required to pay taxes on this income. If participants are paid \$600 or more in total within a calendar year for participation in one or more research studies, the University will report this as income to the IRS and participants may receive an Internal Revenue Service (IRS) Form 1099. If you have any questions or

concerns about this, please contact your UAS help desk staff. This does not include any payments you receive to pay you back for expenses like parking fees.

DATA COLLECTED

We will collect three types of data. First, the self-reported demographic and health data you provide to UAS on a regular basis. Second, our core and recurring surveys will collect information about your health such as your self-reported physical and mental health, diet, sleep habits, experiences with the healthcare system and providers, etc. Finally, we will collect data from your Fitbit outlined below.

- Steps: steps per minute
- Heart rate; resting heart rate
- Device: battery level, device version, last sync time
- Sleep: sleep stage; efficiency; minutes asleep; minutes in bed all day; start time; minutes asleep all day

Using these metrics, we will calculate a set of secondary metrics including daily resting heart rate, average daily steps, sleep architecture, and circadian rhythm.

HOW WILL YOUR DATA BE KEPT SAFE

We take several steps to keep your Study Data confidential. First, only UAS staff will have access to any personally identifiable data. The ALiR study team will only have access to DEIDENTIFIED study data that is linked only to your ALiR study ID number.

When you setup your Fitbit account, any information (including personal information) you provide on the Fitbit app will be transmitted to Fitbit as part of their [Terms of Service](#). However, Fitbit does not retain personal information, and **no personal information will be sent from Fitbit to the study team**. UAS will continue to securely maintain your personal or contact information.

Your Deidentified Study Data will be stored securely at all times on limited access, encrypted servers. Only authorized staff can view Study Data and all analysis will be conducted using Deidentified Study Data.

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) and Human Subject's Protections Program (HSPP) may review your records. Organizations that may also inspect and copy your information include the study sponsor, National Institutes of Health (NIH).

Your data collected as part of this research will be used or distributed for future research studies without your additional informed consent. Any information that identifies you (such as your name) will never be in the data when it is shared with others or used in future research studies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

RISKS OR DISCOMFORTS

This is a minimal risk study, which means that the risk of experiencing any harm or discomfort in this study is not greater than the risk you would encounter in daily life. Some questions may make you feel uncomfortable or distressed. You can choose to stop the study at any time or skip any question. There are potential privacy and security risks that your study information could be subject to unauthorized access or your data could be linked to you. We plan to minimize the possibility of a breach of confidentiality by instituting data safeguarding procedures and state of the art encryption.

BENEFITS

You may or may not receive any benefit from being in this study. You will not receive any treatment as part of this study. You may gain new insight about your activity, fitness, sleep, and overall health through wearing your Fitbit and viewing your Fitbit data. If you take part in this study, the results may help the investigators study how digital technologies can better be used to collect health data.

ALTERNATIVES

An alternative would be to not participate in this study. Whether you participate in this study or not will not impact your participation in other UAS studies.

VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to.

PARTICIPANT TERMINATION

You may be removed from this study without your consent for any of the following reasons: you do not

follow the investigator's instructions, at the discretion of the investigator or the sponsor, or the sponsor closes the study. If this happens, the investigator will discuss other options with you.

CONTACT INFORMATION

If you have questions or concerns about this study, you can get in touch with Tania Gutsche at tgutsche@usc.edu and (213) 821-1819.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877.

Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.