

Title of the Project: Identifying Ambulatory Behavioral and Environmental Associations with Epigenetic and Genetic Profiles
Principal Investigator: Frances Champagne, PhD, Professor
Faculty Advisor:

Consent to Participate in Research

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to aims to better understand the relationship between behavior, psychology, and environment with biological variables.
- In order to participate, you must be 18-35 years old and willing to consent to participation.
- If you choose to participate in this 4-8 week study (depending on the study start date), you will be asked to participate in at least one of two components of the study:
 - 1) personal and home monitoring for the entire study period or
 - 2) biosampling which involves providing saliva, hair and skin swab samples at the beginning and end of the study period
- Possible risks or discomforts from this research include discomfort from answering queries about your mood and stress level and breach of confidentiality.
- The possible benefits of this study include personalized feedback about your sleep/activity patterns, mood and stress reports and specific aspects of your home/dorm environment. Societal benefits include potentially identifying behavioral, psychological and environmental factors that influence human biology
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

You have been asked to take part in a research study that aims to better understand the relationship between behavioral, psychological, and environmental variables with genetic and epigenetic markers, as well as chronic cortisol levels. This study will use cutting-edge technologies to more accurately measure behavioral, psychological, and environmental variables such as such as sleep, activity, fluctuating mood and stress levels, and home/dorm

environmental characteristics. It will examine associations with genetic and epigenetic variants, as well as chronic cortisol to improve our understanding of how these factors contribute to human biology.

What will happen if you take part in this study?

If you agree to be in this study, you will be asked take part in a 4-8 week study period (depending on the study start date).

This begins by your visiting a study specific “store front” located in the Flawn Academic Center (FAC). A team of trained research assistants will answer questions about the research, obtain signed informed consent, issue and instruct in the use of study related equipment and collect samples.

If you elect to participate in the activity monitoring, ecological momentary assessment (EMA) and home monitoring, you will be issued 3 study related equipment: 1) a personal activity monitoring band, 2) a smart phone application, and 3) a home monitoring hub.

After retrieving the equipment, you will be asked to do the following for the study period:

- Continuously wear the activity band on your non-dominant wrist except when it is otherwise inappropriate to wear the device such as when swimming or showering.
- Setup the home beacon device as instructed, swab collect samples in the home and wear a silicon wrist band and complete a single online form.
- Continue to use your smartphone as you normally would. However, you will be queried each day from time to time to answer questions about your sleep, mood state and about your stress. The elements that will be monitored include:
 - Inertial sensing measures (e.g., accelerometer, gyroscope) data measures gravitational acceleration and can be used to infer levels of physical activity.
 - Location data, which provides latitude, longitude, altitude, and addresses of the users' current location with an accuracy of 250 feet.
 - Device Usage data measures how often users access and use their mobile device.
 - Experience Sampling Method (ESM) uses cues presented at specific times of the day that administer brief survey questions about participant's surroundings or participant's mood and stress (requiring less than a minutes to complete).

The smartphone application will be running in the background and may use more data and phone battery than if the app was otherwise downloaded. While the application collects mobile data in real time, it will only upload data when connected to Wi-Fi to minimize data usage on the part of the individual's cell phone plan.

If you elect to participate in the biosampling, you will be asked to provide:

- Two saliva samples by drooling into a small collection tube, one small hair sample (matchstick in diameter) from the back of the head, and one skin swab sample from your arm at the time of consent/enrollment.
- At the end of the study period, you will be asked to provide one additional saliva sample, one additional hair sample, and one additional skin swab sample.

We will genotype the DNA for a number of genes that are known to differ across people. We will assay the DNA for epigenetic changes across the genome. We will also assay your hair for changes in levels of cortisol. Bacterial communities will be determined from your skin swab samples.

In addition to the new data collection outlined above, we will ask your permission to link data collected as part of this study to:

- Administrative data collected and maintained by the University of Texas (e.g., number of hours completed, year of high school graduation, high school GPA).

Upon completion of the study period, you will be required to return all study related equipment to our FAC location. Failure to return the equipment could result in your being responsible for the cost of each piece not returned.

How long will you be in this study and how many people will be in the study?

Participation in this study will last 4-8 weeks (depending on the study start date). We anticipate a sample size of ~1800 individuals.

What risks and discomforts might you experience from being in this study?

This procedure may involve risks that are currently unforeseeable. Possible risks associated with this study include discomfort from answering queries about your mood and stress level. A possible risk associated with this study is breach of confidentiality. Although this risk exists, we have taken a number of precautions to ensure that personal information is protected and remains confidential.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

We plan to provide you with some personalized feedback about your sleep/activity patterns, mood and stress reports and specific aspects of your home/dorm environment. You may benefit from knowing about your sleep, activity, stress and mood levels during the study period. Other possible benefits of participation are increased knowledge of and interest in genetic and epigenetic research related to behavioral, psychological and environmental variables.

This study also has benefits for society as we will test novel methods for collection of behavioral, psychological, and environmental data in an effort to more accurately assess these variables in research. In addition, we hope to identify behavioral, psychological and environmental factors that potentially influence human biology.

What should you know about the genetic research?

If you elect to participate in the biosampling, we will genotype your DNA for a number of genes that are known to differ across people. We do not plan on sequencing your whole genome from this sample.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes 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:

- Health insurance companies and group health plans may not request your genetic information that we get from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 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.

All health insurance companies, group health plans, and all employers with 15 or more employees must follow this law.

Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it prohibit discrimination on the basis of a genetic disease or disorder that you already know about.

By signing the consent form, you acknowledge that you have voluntarily donated your saliva specimen to the University for research purposes.

What will happen to the samples and/or data we collect from you?

All data and samples being collected will be coded numerically (not the student's EID); as a result, this data will contain no personally identifying information when it is stored, catalogued, and/or processed. Data will only be identified using this numerical code and information tying a specific student to that code will be kept in a separate pass-worded database that is only accessible by the PIs and study staff.

How will we protect your information?

If you wish, you will be given the option of scheduling a private appointment if you prefer to maintain privacy about your participation in the study. Please contact Dr. Schnyer at schnyer@utexas.edu and he will forward your request to the study coordinator.

Electronic data files that merge the collected data with other participant data (course performance data, Canvas page view data) will be stored without personally identifying information (e.g., name, DOB, student EID). An index of identity information that links numerical codes used for participant data with student EIDs will be stored in a separate, password-protected electronic file to which only senior research staff will have access. Consent forms will be kept in locked filing cabinets inside of the laboratory, which is itself locked when not in use.

All electronic records will be stored on a secure UT-Austin, TACC, or AWS Cloud-based computing system for protected data. The web-based portal will be designed and maintained to support data capture for research studies, providing secure log in and user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit

trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Unused samples will be destroyed. Data will be maintained indefinitely.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order.

We may share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you.

The National Institute of Health (NIH) is a federal agency that has a Genomic Data Sharing (GDS) policy that encourages scientists to share deidentified genetic data with other scientists in order to accelerate the pace of scientific discoveries. If you provide your consent below, the genetic data we obtain from your saliva sample would be uploaded to NIH's Database of Genotypes and Phenotypes (dbGaP). The purpose of this database is to create larger datasets that can be used to advance scientific knowledge. Please be assured that all of your identifying information will be removed from your genetic samples before being uploaded to the online database. While we may share the deidentified genetic information with other study investigators, we will never transfer ownership of your samples to other parties.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for data analysis and future research. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

How will we compensate you for being part of the study?

Students who complete the activity monitoring, EMA, and home monitoring will be allowed to keep their activity monitoring device. If they do not wish to keep the activity monitoring device, they can elect to receive a \$50 gift card instead.

Students who complete the biosampling will be compensated in the form of a \$30 gift card and will be entered in a drawing for a \$50 gift card.

Students who enroll within the first week of the study (and complete at least one component of the study) will be offered additional compensation as follows:

- Participants that are part of PSY 301 will earn 2 course credits (enrollment will take up to 1 hour and completion of the study will take up to 1 hour).
- UT Austin students who are not enrolled in PSY 301 will receive a \$10 gift card.

PSY 301 students who complete at least one component of the study will earn an additional 2.5 credits (each component takes at least 2.5 hours, this will be in addition to the monetary compensation offered).

Gift cards will be issued when the devices are returned to the “store front” and/or when the final samples are collected at the end of the study period. Course credit will be issued by the end of the semester. Students who elect to participate will also receive print outs of some of their data such as a sleep activity summary chart.

Who can profit from study results?

Your samples may be used for commercial profit and there is no plan to share those profits with you.

What other choices do you have if you do not take part in this study?

PSY 301 students may elect to participate in an alternative study.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

Prior, during or after your participation you can contact the PI, Frances Champagne (fchampagne@utexas.edu OR 512-232-3401) or the researcher David Schnyer (schnyer@utexas.edu OR 512-475-8499) for any questions or if you feel that you have been harmed.

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference study number 2019-09-0120.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

(a)

_____ I **do** agree to wear an activity band, install a smartphone application, respond to a few queries/day, and place a small monitoring device in my living space for the study period.

_____ I **do not** agree to wear an activity band, install a smartphone application and respond to a few queries/day, and place a small monitoring device in my living space for the study period.

(b)

_____ I **do** agree to submit three saliva samples for genotyping and epigenetic analysis, two hair samples for cortisol testing, and two skin swab samples for skin microbiome testing.

_____ I **do not** agree to submit three saliva samples for genotyping and epigenetic analysis, two hair samples for cortisol testing, and two skin swab samples for skin microbiome testing.

(c)

_____ I **do** agree that my data can be used by the study investigators for research purposes. This will involve the study investigators linking my data to other data being collected by the University of Texas, including administrative data collected and maintained by the University of Texas (e.g., number of hours completed, year of high school graduation, high school GPA).

_____ I **do not** agree that my data can be used by the study investigators for research purposes.

(g)

_____ I **do** agree that my deidentified genetic information can be shared with other researchers, including contribution to NIH dbGaP.

_____ I **do not** agree that my deidentified genetic information can be shared with other researchers, including contribution to NIH dbGaP.

Printed Subject Name

Signature

Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

Print Name of Person obtaining consent

Signature of Person obtaining consent

Date