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| STUDY INFORMATION |

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| *For studies following a multi-center or sponsor protocol, please use this* [*guidance*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Guidance-Submitting-Sponsored-Protocols.docx) *to assist in your completion of this form.*  *For questions regarding definitions, policies, or terms referenced below see the* [*policies and procedures manual*](https://research.utexas.edu/ors/human-subjects/policies-and-procedures/)*.* |

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| Study Title and Number from IRBaccess |
| Identifying Ambulatory Behavioral, Psychological and Environmental Associations with Genetic and Epigenetic Profiles |
| 2019-09-0120 |

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| Principal Investigator | | | |
| Name | Position | UT EID | E-mail Address |
| Frances Champagne | Professor | fac752 | franceschampagne@utexas.edu |
| If principal investigator is a student, describe how the PI is qualified/trained to conduct this study. | | | |
| Click or tap here to enter text. | | | |

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| Faculty Sponsor *(required if the PI is a student)* | | | |
| Name | Position | UT EID | E-mail Address |
| First Last | Title | XXX## | jdoe@utexas.edu |
| Describe how faculty sponsor will oversee the conduct of the study. | | | |
| Click or tap here to enter text. | | | |

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| Primary Point of Contact (if different from PI) | | | |
| Name | Position | UT EID | E-mail Address |
| First Last | Title | XXX## | jdoe@utexas.edu |

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| Additional Research Staff | |
|  | Research staff other than the principal investigator will conduct human subject research. |
| *If additional personnel will be engaged in conducting research* *human subject research, complete and upload the* [*Research Personnel Form*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Personnel-Form.docx)  *Engaged in human subject research is defined as contact or interaction with research participants through recruitment, informed consent process, data collection, analysis of or access to identifiable research data.* | |

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| Purpose and Rationale for Conducting Research |
| Hypothesis |
| Few studies have attempted to deliver on the promise of using smart technologies to gain a deeper understanding of the relationships between behavior, psychology, environment and biology. |
| Study Background |
| Prospective, longitudinal, community-based cohort studies are critical for understanding developmental phenomena in context, and for elucidating complex processes such as risk and resilience (Wilson et al. 2015). Despite the wealth of knowledge generated from studies using such designs, the implementation of this approach has relied on traditional methods of measurement and data integration that do not capture the dynamic processes and rich contexts that contribute to health and development. Fortunately, recent advances in smart technologies and the Internet of Things coupled with machine learning and edge computing techniques promise the transcendence of these traditional approaches (Burke et al., 2017; Eskofier et al., 2017; Lane et al. 2010; Schmitter-Edgecombe, Cook, Weakley & Dawadi, 2017). These technological advances offer opportunities to passively collect real-time data on a wide range of social-behavioral and health variables with less participant burden and more ecological validity than ever before (Ginexi et al. 2014), potentially addressing some of the key limitations of the traditional prospective, longitudinal cohort study (Lerner 2002). For example, over the last decade, objective measures of food intake (Thomaz, Essa and Abowd 2015), sedentary behaviors (Bae, Dey and Low 2016), activities of daily living (Thomaz et al. 2012), daily social activities (Mehl, 2017), alertness (Abdullah et al. 2016) and health status (Madan et al. 2010) have been inferred from mobile and environmental sensors. |
| Design and Methodology |
| The current proposed project will begin to address these challenges by developing and deploying cutting-edge technologies that aim to more accurately measure behavioral, psychological, and environmental variables such as sleep, activity, fluctuating mood and stress levels, and home/dorm environmental characteristics. In addition, by collecting and examining genetic and epigenetic markers, as well as chronic cortisol levels, we aim to better understand how behavioral, psychological and environmental factors contribute to human biology. |
| Data Analysis |
| TBD |

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| Funding and Regulatory Oversight | | | | | |
| *Check all agencies that fund or hold regulatory oversight over the research activities.*  *If study activities are regulated by the FDA, check FDA here. The FDA regulates any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit..* | | | | | |
|  | Food and Drug Administration (FDA) Regulated | | | | |
|  | NIH |  | Department of Defense (DoD) |  | Dept. of Education (DoEd) |
| *Complete* [*Supplemental IRB Application - DoD*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-DoD-1.docx) |
|  | Dept. of Energy (DOE) |  | Department of Justice DOJ/NIJ |  | Environmental Protection Agency (EPA) |
|  | Bureau of Prisons |  | | | |
|  | Other Federal Agencies: Click here to enter text. | | | | |
|  | Industry/Private Sponsor: Click or tap here to enter text. | | | | |
|  | UT Funding Account Number: Click or tap here to enter text. | | | | |
|  | Other External Funding: Click or tap here to enter text. | | | | |
| OSP: This research will be supported by the Office of the Vice President for Research and their Bridging Barriers Initiative. | | | | | |

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| PROCEDURES |

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| Study Elements | | | | | | | |
| *Check any that apply to your study. This is not meant as a comprehensive record of your entire study.*  *A full description of all study procedures should be provided in the procedures section below or the applicable supplement form.* | | | | | | | |
|  | Bio-specimen | | |  | Biometrics |  | Registry or repository |
|  | *Complete* [*Supplemental IRB Application – Biospecimens*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Biospecimen.docx) | | |  |  |  | *Complete* [*Supplemental IRB Application - Repository*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Repository.docx) |
|  | Focus Group | | |  | Genetic Analysis |  | Genomic Data Sharing |
|  | International research | | |  | Interview/ Survey |  | MRI |
|  | Complete [Supplemental IRB Application - International](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-International.docx) | | |  |  |  |  |
|  | PHI | | |  | Observation |  | Record Review (Prospective) |
|  | *Complete* [*Supplemental IRB Application - PHI*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-PHI.docx) | | |  |  |  |  |
|  | Record Review (Retrospective) | | |  | Screening Procedures |  | Sensors (Externally Placed) |
|  | Sensors (Inserted) | | |  | Video/Audio Recording |  | X-Ray |
| Interventions | | | | | | | |
|  | Drug/Biologic | | |  | Device |  | Behavioral |
|  | *Complete* [*Supplemental IRB Application - Drugs*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Drugs-1.docx) | | |  | *Complete* [*Supplemental IRB Application - Device*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Device.docx) |  |  |
| Additional Oversight | | | | | | | |
|  | | Biohazards, Recombinant DNA, or Gene Transfer |  | | Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos |  | Radiation exposure without direct clinical benefit |
|  | | Upload IBC approval letter |  | |  |  | Upload radiation safety approval |
| Additional Questions: | | | | | | | |
|  | | This study involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. | | | | | |

| Procedures |
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| Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:   1. All study procedures, in sequential order 2. All research measures/tests that will be used (state if questions or measures are standardized or published) 3. Secondary data or specimens that will be obtained, how they will be collected, and how they will be used 4. Where each activity will take place, the duration of each, and who will perform each activity 5. Include time commitment of participants 6. Mark all optional procedures as [OPTIONAL] |
| **Study Timeline:**  Data collection will span 2 consecutive semesters in the regular academic year (Fall/Spring), and we anticipate conducting analyses on this data for up to 5 years from the beginning of the study. Any given student will participate during a single 4-8 week period (depending on IRB approval and study start date). We anticipate conducting up to two 4-8 week study periods each semester.  **Measures:**   1. **Activity Monitoring**: At the consent/equipment session, if participants are willing and eligible, they will be given an activity tracking device to wear which will record their sleep/activity cycle. Participants will wear this device continuously for the study period. In addition, participants will be asked to complete a short diary assessment each morning. Participants will log into a secure web-based survey site and complete a survey which will include a sleep log for the prior night. 2. **Ecological Momentary Assessment (EMA)**: At the consent session, if participants are willing and eligible, mobile data will be collected from each participant's respective personal mobile devices using an open-source mobile phone application for the study period. One example of the type of software that may be used is the Beiwe system developed at Harvard University with funding from the NIH (citation https://www.ncbi.nlm.nih.gov/pubmed/26543914). Mobile data collection (via daily questions, accelerometry, location patterns, ambient noise, device usage, communication, and weather) will allow us to apply an advanced experience sampling approach to gain a more fine-grained understanding of behavioral patterns of students in their day-to-day natural environment.   All mobile data will be pushed to a highly secure and encrypted remote cloud server services provided by the Texas Advanced Computing Center and/or Amazon Web Services. Mobile data will include a variety of metrics from built-in sensors and plugins that are available on all recent Android and iPhone models and will include the following:   1. **Inertial sensing measures** (e.g., accelerometer, gyroscope) data measures gravitational acceleration and can be used to infer levels of physical activity. 2. **Location data**, which provides latitude, longitude, altitude, and addresses of the users' current location with an accuracy of 250 feet, with minimal battery impact. 3. **Device Usage** data measures how often users access and use their mobile device. 4. **Experience Sampling Method** (ESM) uses cues presented at specific times of day that administer brief survey questions about participant's surroundings or participant's mood and stress (requiring less than a minutes to complete). Queries will be made pseudo-randomly within four 4-hour time blocks during normal waking hours, with no two samples arriving within the same hour. Surveys will consist of a brief series of Likert scale questions.   No personal identifiers (including any account or identifying information, e.g., social media accounts, usernames, passwords, etc.) will be collected by the application and no data from other applications will be accessed. Moreover, no additional personal information beyond the scope of the data modalities described above will be collected intentionally or incidentally as part of this study, including personal calendars, e-mail, contacts, social media, pictures, etc.  The specific application used will be open source so that it can be legally modified as needed by expert programmers on-site to comply with the University of Texas Austin's privacy and technology security requirements. Accordingly, there are no obligations to communicate any protected or sensitive data to the application developers or any third party under any circumstances now or at any future time. The researchers on this protocol will own the data from the subjects and it will not be made publicly available. Copies of the data will not be available or accessible to the application developers and data will be stored on a secure UT-Austin, TACC, or AWS Cloud-based servers. In sum, the open-source nature of the application facilitates streamlined protection of the study data on the part of UT ITS and study research staff.  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.  The mobile data obtained from this application will be linked to the specific subjects via a hash-tagged ID incorporated into the application. This ID will only be recorded into the password protected secure data portal to ensure confidentiality and privacy. At this time, there are no plans to have any persons or research staff directly access the mobile data in real-time.  **c. Home Environmental Monitoring:**  Students participating in the home environmental monitoring component of the study will be provided with a home monitoring kit that will consist of the following:   * + A set of small real-time sensors to measure indoor temperature, light, relative humidity as well as carbon dioxide, particulate matter, carbon monoxide, sulfur dioxide, nitrogen dioxide, ozone and volatile organic compound concentrations in the participant's home/dorm, each recorded at 15sec-15min resolution.   + These monitoring systems will consist of commercially available sensor chips (e.g., sourced from adafruit.com or equivalent) coupled to a Rasberry Pi unit (or equivalent). The participants will be asked to plug the central unit in and then place the modular sensors in several locations within their home, dorm or apartment for the study period. These locations may include their living room (if applicable), bedroom or kitchen (as applicable). In homes or apartments where outside air quality data can be readily collected, sensors will also be placed immediately outside the home to compare against the indoor monitoring data. Data collected on the home monitoring device will be pushed to a secure UT-Austin based server created and maintained in close collaboration with UT-Austin ITS personnel.   + A set of 5-6 swabs to collect surface dust samples from several locations in the home, as well as one from one UT classroom desktop and one from the participant's cell phone. Specifically, participants will be asked to collect swab samples from (1) the top of the door trim exterior to their living unit, (2) the top of the door trim interior to their living unit, (3) a 1ft2 area of the living room floor, (4) the surface of the heating, ventilation and air conditioning a (HVAC) filter if readily available in the home, dorm or apartment, (5) the surface of one of desktops they use in a UT Austin classroom and (6) the front face of their cell phone. These samples will be processed to determine the microbial (fungal and bacterial) communities present in the participants’ homes, classrooms, and cell phones.   + A flexible wristband (e.g., silicon, or equivalent) that participants will be asked to wear during the study period. This wristband will adsorb semi-volatile organic compounds and be used to assess participant exposures to semi-volatile compounds in their home and daily life.   Students participating in the home monitoring component of this study will complete the “Questions for Home Environment Monitoring Participants” through a secure online portal.   1. **Biosampling.**   If participants are willing and eligible, students who elect to participate in the biosampling will provide:   * Two hair samples (matchstick in diameter) from the back of the head to determine changes in levels of hair cortisol. Hair cortisol is a method for determining chronic levels of cortisol without the burden of repeated saliva sampling to assess long-term cortisol levels. * One saliva sample to have their DNA genotyped for a number of genes that are known to differ across people to determine polygenic scores related to psychological variables. * Two saliva samples to determine genome-wide changes in epigenetic markers. Previous research has identified epigenetic changes due to smoking and age. However, little is known about how other variables, such as stress, affect our epigenome. * Two skin swab samples to determine the bacterial community present on their skin (i.e., skin microbiome).  1. **Administrative data**.   We will ask for student consent to link this data with information already being collected as part of this study and 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).  **Consent and Study Initiation:**  This will begin by visiting a study specific “store front” located in the Flawn Academic Center (FAC). A team of trained research assistants will be available in order to answer questions about the research, obtain signed informed consent, issue and instruct in the use of study related equipment and collect samples.  Students who elect to take part in the activity monitoring, ecological momentary assessment (EMA), and home monitoring will be issued 3 study related equipment: 1) a personal activity monitoring band, 2) a smart phone application, and 3) a home monitoring hub.  Students who elect to participate in the biosampling (genotyping, epigenetics, hair cortisol analysis, skin microbiome) will provide two saliva samples, one small hair sample (matchstick in diameter) from the back of the head, and one skin swab sample from the inner elbow at the time of enrollment. At the end of the study period participants will provide one saliva sample, one additional hair sample and one skin swab sample.  **Location:**  Data collection will take place on the students’ person as they go about their everyday life as well as in their home and dorm environment. Sample collection will occur at the “store front” as well as in their home and dorm environment. Additional data collection will occur online through the Canvas system. |

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| Alternatives to Participation in this Study |
| Participation is voluntary. Participants may decide not to participate at all or, if they start the study, may withdraw at any time. PSY 301 students have the option to participate in other studies posted in SONA. |

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| LOCATIONS |

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| Study Locations | | | | | |
| Identify the sites where study activities will occur under the direction of UT Investigators. | | | | | |
|  | UT Austin |  | UT Health Austin |  | Dell Seton Medical Center |
| *Upload S.A.T. submission receipt* |
|  | Dell Children’s Medical Center |  | K-12 schools/district |  | Day care center |
| *Upload S.A.T. submission receipt* |
|  | Seton Medical Center Austin |  | CommunityCare |  | |
| Upload S.A.T. submission receipt |

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| External Locations | | |
| Include any non-UT site where UT or non-UT personnel will conduct consent, data collection, intervention, or analysis of identifiable data under the direction of the UT principal investigator.  *If UT Austin will serve as the reviewing IRB for a multi-site study (study involves collaboration with sites or individuals external to UT Austin who are engaged in human subjects research), contact RSC to verify the UT IRB will serve as the reviewing IRB.*  *Once verified, each relying site must complete the* [*IRB Reliance Form*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/05/Site_Specific_Application_for_Relying_on_UT_IRB.docx)*.* | | |
| Site Name | | IRB Oversight Plan |
| Click or tap here to enter text. | | Select IRB Oversight. |
| Additional Questions | | |
| Will UT act as a central coordinating site? | | No |
| Describe procedures to communicate SAEs, UPs, and modifications to external sites. | Click or tap here to enter text. | |

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| SUBJECT POPULATION |

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| Protected Subject Populations | | | | | |
| Select all populations specifically studied under this research. | | | | | |
|  | Active military personnel |  | Children |  | Decisionally impaired adults |
|  | Emancipated minors |  | Fetuses |  | Individuals with limited English proficiency |
|  | Neonates |  | Pregnant women |  | Prisoners |
| *Complete* [*Supplemental IRB Application - Repository*](https://research.utexas.edu/wp-content/uploads/sites/3/2018/10/Supplemental-IRB-Application-Prisoners.docx) |
|  | UT Students |  | | | |

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| Research Participant Information | | | | |
| *Describe the research population.* | | | | |
| Participant Groups: | * UT students | | | |
| Age range | 18 | To | 35 |  |
| Gender | Any | | | |
| Inclusion criteria | All who consent to participate. | | | |
| Exclusion criteria | Participants will be excluded if they are under the age of 18 and cannot consent to participation. | | | |
| Population info | Students will be recruited from the introductory psychology class (PSY 301).  In addition to the PSY 301 pool, we will recruit from the general UT Austin student population.  Anticipated sample size is ~1800 students. Inclusion in the study will be voluntary. | | | |

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| Total Sample Size | |
| Total number of participants  for all participant groups | N = 1800 |
| Sample size rationale | To detect small effects. |

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| SCREENING & RECRUITMENT |

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| Identification and Screening | |
|  | This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:   1. Oral or written communication with the prospective subject or LAR 2. By accessing records containing identifiable private information or stored identifiable biospecimens |
|  | Describe the identification and/or screening procedures: |
| N/A |

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| Recruitment | | | | | |
| *Select all recruitment methods utilized for this research and describe the recruitment process.*  *Upload copies of recruitment materials/scripts to IRBaccess.* | | | | | |
|  | E-Mail |  | Flyer |  | In-Person |
|  | Letter |  | Social Media |  | Research Pool |
|  | Telephone/Text |  | Snowball sampling |  | Web-posting |
|  | Word of Mouth |  | Other: electronic bulletin boards | | |
| Describe the recruitment process including where recruitment will take place. | | | | | |
| Online, through-out the UT campus or as an in-class announcement | | | | | |

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| OBTAINING INFORMED CONSENT |

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| Consent Overview | | | |
| Select all applicable.  See IRB [Policies and Procedures](https://research.utexas.edu/ors/human-subjects/policies-and-procedures/) Section 6 for a description of informed consent.  See IRB [Policies and Procedures](https://research.utexas.edu/ors/human-subjects/policies-and-procedures/) Section 12.4 for a description of assent/parent permission. | | | |
|  | Obtaining Written Consent |  | Requesting Waiver of Documentation of Informed Consent |
| *Complete the Consent and Assent Processes section below* | *Complete the Consent and Assent Processes and the Waiver of Documentation of Consent sections below* |
|  | Requesting Waiver of Informed Consent |  | Requesting Alteration of the Required Elements of Informed Consent |
| *Complete Waiver or Alteration of Informed Consent section below* | *Complete Waiver or Alteration of Informed Consent section below* |
|  | Obtaining Child Assent |  | Obtaining Short Form Consent |
| *Complete the Consent and Assent Processes section below* | *Complete the Consent and Assent Processes section below* |

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| Consent and Assent Processes |
| Provide a detailed description of the consent process including who will obtain consent, where, and when consent will occur in such a manner that participants have sufficient time for adequate consideration. |
| Students will give signed consent when they visit the study “store front”. Trained research staff will be available to answer any questions and make sure that participants understand risks and benefits. No course instructors/researchers will be at the “store front” when student participants are present and the trained research staff will be collecting Consent Forms and will securely store them away from PIs until the end of the semester. |
| Upload consent forms, script, or letter to IRBaccess. |

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| Waiver of Documentation of Consent | | |
| To approve a waiver of documentation of informed consent, one of the following criteria below must be justified by the researcher.  Only complete the section below if requesting a waiver of documentation of informed consent. | | |
| Waiver Option 1   1. The only record linking the subject and the research would be the consent document 2. The principal risk would be potential harm resulting from a breach of confidentiality. 3. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. | | Click or tap here to enter text. |
| Upload consent forms with and without signature lines.    Include this choice in the informed consent form.  Articulate the destruction protocol for signed consent forms in the privacy and confidentiality section. |
| Waiver Option 2   1. This study is minimal risk. 2. Written consent would not be required outside of the research context | Click or tap here to enter text. | |
| Upload consent form to IRBaccess. | |
| Waiver Option 3   1. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm 2. the research presents no more than minimal risk of harm to subjects. 3. There is an appropriate alternative mechanism for documenting that informed consent was obtained. | Click or tap here to enter text. | |
| Upload consent form to IRBaccess | |

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| Waiver or Alteration of Informed Consent | | | |
| To approve a waiver of informed consent, all of the following criteria must be justified by the research. Provide a protocol specific justification for each.  Only complete the section below if requesting a waiver of informed consent or alteration of informed consent. | | | |
| The research involves no more than minimal risk to the subjects. | | Click or tap here to enter text. | |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects. | | Click or tap here to enter text. | |
| The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent). | | Click or tap here to enter text. | |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. | | Click or tap here to enter text. | |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | |  | Additional pertinent information would not be appropriate (*e.g.*, no deception). |
|  | Additional pertinent information is appropriate. |
|  | Research that requires alteration of informed consent on the grounds that deception is necessary must complete the deception section below. |
| Deception | | | |
| See IRB [Policies and Procedures](https://research.utexas.edu/ors/human-subjects/policies-and-procedures/) Section 15 for a description of deception. | | | |
| Describe the nature of deception | | Click or tap here to enter text. | |
| Why is deception required? | | Click or tap here to enter text. | |
| Describe debriefing procedures | | Click or tap here to enter text. | |
|  | Research participants will have the opportunity to withdrawal their data during the debriefing. | | |
| ­Upload debriefing form to IRBaccess. | | | |

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| Consent Translation | | |
|  | The study population will likely include participants whose limited English speaking status requires translation of the consent form. | |
| The IRB recommends having English versions of consents approved prior to translation.  When available, upload translated documents to IRBaccess.  See [IRB Policies and Procedures](https://research.utexas.edu/ors/human-subjects/policies-and-procedures/) Section 6.4.1 for a description of translation procedures. | | |
|  | The consent documents will be translated by a certified translator. | |
|  | A non-certified translator will translate the consent documents. | |
| Describe the translator’s qualifications | |
| Click or tap here to enter text. | |
|  | Documents will be translated, and the research team will attest that the translation is accurate and appropriate. |
| Upload translated documents and attestation (if required) to IRB Access. | | |

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| RISKS AND BENEFITS |

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| Benefits | | |
| *Compensation for time and effort is not considered a benefit.* | | |
| Benefits to Society | | Describe scientific and societal benefit. |
| 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. |
| Direct Benefit |  | No potential for direct benefits to participants |
|  | Describe potential for direct benefits to participants. |
| All participants will receive personalized feedback about their sleep, activity, behavioral patterns, mood and stress levels, and specific aspects of their home/dorm environment. Participants will be provided with informational material to understand their personalized feedback. Students will learn about their own sleep, activity patterns, mood and stress fluctuations and home environment. Students will also learn about genetic and epigenetic research related to behavioral, psychological and environmental variables. |

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| Risks | | |
|  | Greater than Minimal Risk Study | |
| Complete the Data Safety and Monitoring Plan section below. | |
| Research related risks only pertain to risks associated with procedures required by the study; do not include risks of any procedures that the participant would undergo if not participating in the study. | |
| Describe the risk(s) associated with the research. | |
| This procedure may involve risks that are currently unforeseeable. Possible risks associated with this study include discomfort from answering queries about mood and stress levels. A potential risk is breach of confidentiality, because identifying information will be collected and could be linked to participants’ genetic information. Although this risk exists, we have taken a number of precautions to ensure that personal information is protected and remains confidential. There are no known risks of participants being provided with their own data and having that data compared to other members of their peer group. | |
| Describe the risk mitigation plan | |
| While this may cause some anxiety among some students, to mitigate potential harms, students will be educated regarding the normal range of behaviors and what they can do if they feel they are experiencing activities/feelings outside of that range – e.g. sleep difficulties or elevated stress levels. Students will be given a list of referrals in case they want more information about how to deal with these potential difficulties and study staff will also be available to provide the appropriate referral. | |

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| Data Safety and Monitoring Boards (DSMBs) and Plans (DSMPs) | |
|  | This study will have a DSMB. |
|  | Describe the DSMB including frequency of meetings, members, data reviewed, and stopping points. |
| Click or tap here to enter text. |
|  | The study will have a DSMP. |
|  | Describe the DSMP, including what data or responses are monitored, when data is reviewed, and what actions are taken to react to a safety concern. |
| Click or tap here to enter text. |

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| Required Consent Disclosures | | | |
| Child and Elder Abuse | | | |
| Texas law requires that anyone report suspected child/elder abuse or neglect. | | | |
| Is it likely investigators could discover information that would require mandatory reporting by the investigators or staff? | |  | Yes, it is likely. |
| Include mandated reporting language in applicable informed consent document(s). |
|  | No, it is not likely. |
| Incidental Findings | | | |
| Incidental findings include: genetic markers, concerning test results, disease, suicidal thoughts, unexpected paternity, engaging in illegal activities. | | | |
|  | It is possible that investigators could discover incidental findings or other information about a participant's previously unknown condition. | | |
|  | If so, state methods for addressing and reporting incidental findings | | |
| Click or tap here to enter text. | | |
| *Include incidental report information as applicable in the informed consent document(s).* | | |

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| Early Withdrawal |
| List the criteria for withdrawing individual participants from the study (*e.g.*, safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor). |
| Participation is voluntary. Participants may decide not to participate at all or, if they start the study, may withdraw at any time. |
| Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early. |
| Click or tap here to enter text. |
| Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns. |
| Click or tap here to enter text. |
| If any of the above are applicable, include this information in your consent form. |

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| PRIVACY AND CONFIDENTIALITY |

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| Privacy |
| Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants. |
| Include information regarding privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data. |
| Students will be issued and collect their devices during a “store front” drop-in session, which can reveal to other student participants that they are electing to be in this portion of the study; however, students will be given the option of scheduling a private appointment if they prefer to maintain privacy about their participation in the study. |

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| Confidentiality and Data Security Plan | | |
| Describe how you will protect the confidentiality of data or address confidentiality concerns. | | |
|  | Identifiers will be coded to protect confidentiality. | Describe how data is coded and where identifiers are stored. |
| 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. |
|  | Identifiable data will be destroyed. | Describe destruction plan and timeline |
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|  | Identifiable data will not be destroyed. | Provide rationale for retaining identifiable data indefinitely. |
| Click or tap here to enter text |
| Describe how you will store and secure your data (including length, location, and medium of storage): | | |
| Electronic data files that merge the collected data with other participant data (course performance data, Canvas pageview 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. | | |

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| Data Access | | | | | |
|  | Study team members |  | Collaborators |  | Data coordinating center |
|  | Sponsor |  | Future sharing with other researchers |  | Other: NIH dbGaP |
| Describe Data Sharing (If Applicable) | | | | | |
| 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. | | | | | |

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| Certificate of Confidentiality | | |
| *See* [*IRB Policies and Procedures*](https://research.utexas.edu/ors/human-subjects/policies-and-procedures/) *Section 4.11.5 for a description of a Certificates of Confidentiality.* | | |
|  | The study does not require a Certificate of Confidentiality. | |
|  | The study requires a Certificate of Confidentiality. | |
|  |  | NIH has issued a Certificate of Confidentiality for this study. |
|  | A Certificate of Confidentiality has not been obtained, but there are plans to apply for one. |

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| COMPENSATION AND COSTS |

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| Compensation | | | | | |
|  | Subjects receive compensation. | | | | |
|  | Subject will not receive compensation. | | | | |
| Total amount of compensation | | | 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. | | |
| Proration schedule | | | N/A | | |
| When do subjects receive compensation? | | | By the end of the study period or by the end of the semester. | | |
| Select the form(s) of compensation | | | | | |
|  | Cash |  | Check |  | Gift Card Click or tap here to enter text. |
|  | Course Credit |  | ClinCard |  | Other: Click or tap here to enter text. |
|  | Compensation amount and type reasonable for this population for the activities requested of them. | | | | |
| Click or tap here to enter text. | | | | |

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| Costs | | | |
| Select all categories of costs for which participants or their insurance companies will be responsible. | | | |
|  | Participants will have no costs associated with this study | | |
|  | Standard of care procedures contributing to study data |  | Research procedures not associated with standard of care |
|  | Administration of drugs / devices |  | Study drugs or devices |
|  | Transportation and parking |  | |
|  | Other: Click or tap here to enter text. | | |

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| REQUIRED DOCUMENTS |

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| Additional Supporting Documents | |
|  | Principal Investigator CV - Required |
|  | Faculty Sponsor CV – Required for student PIs |
|  | Recruitment Materials |
|  | Consent, Parental Permission, and Assent Forms |
|  | Measures and Instruments |
|  | Sponsor Protocol |
|  | Investigator Brochure |
|  | Personnel Form |
|  | IDE/IND Verification |
|  | Supplemental Forms |