Section 4 IRB Protocol

*required

6 Anticipated number of subjects for the entire project.

200

7 Submission type

Exempt study

Secondary Analysis of Existing Data

✓ All other studies

*required

Purpose of the study

a) **Study Goal**. Provide a concise statement of the study hypothesis(es) or goal(s).
b) **Literature review.** Briefly describe how the pertinent body of literature supports the study goal. Include citations and references.
c) **Citations and references**. Include citations and a complete reference section.
d) **Possible contribution**. Describe the potential benefits of the proposed research study to the literature.

Study Goal: This study aims to answer several key questions in the computational, behavioral, and data science domains. First, we want to study how computational models can detect, distinguish, and/or predict key stressors (i.e., stress event precipitants) from sensor data in peoples' day-to day lives. Second, we want to investigate methods for representation of data at the individual- and population-level that helps participants increase their awareness of their daily stress patterns. Next, , we expect to observe within- and between-subjects differences in stressor "phenotyping" using sensor-detected stress episodes – that has previously been largely limited to self-reported items. We want to investigate how these phenotypes can be used to develop new, temporally-precise stress interventions. Finally, we want to investigate the capacity for building and testing an effective structure for mHealth metadata that can inform a variety of mHealth use cases, e.g., including (1)

mHealth privacy (i.e., of data collection) and (2) data missingness/deterioration (i.e., how should data missingness – including from engaging privacy functions – be annotated?).

As such, this study is designed to advance extant research in the objective, automatic detection of stress and stressors via mobile sensors in a holistic manner that advances science in several domains.

The use of mobile health (mHealth) technologies is rapidly developing. This rapid advancement, coupled with advancements in mobile health big data analytics, make the monitoring of health in individuals' natural environments increasingly feasible (Kumar et al., 2015). The continuous, in the field monitoring of stress, for example, may have implications on myriad health outcomes, including via mobile-deployed interventions (Hovsepian et al., 2015; Sarker et al., 2016). However, current interventions are typically one-size-fits-all, are not tailorable to context, set, or setting, and only approach from limited domains (e.g., mindfulness).

Technologies including "smart watches" (wrist-worn suites of mobile sensors) are commercially available for activity tracking purposes (e.g., as pedometers, sleep quality trackers). Nascent and promising research on wrist-worn technologies has demonstrated a utility for the characterization of health-related behaviors. For example, the in-the-field detection of active/sedentary behavior has been demonstrated using wrist-worn devices (Zhang, Rowlands, Murray, & Hurst, 2012). Wrist-worn sensors have also been used in concert with other sensor suites (e.g., AutoSense) to detect instances of stress and smoking in the field (Saleheen et al., 2015; Sarker et al., 2016).

Stress detection is a key target in the National Institutes of Health initiative to discover the Science of Behavior Change, as stress is a "key risk factor for negative health outcomes" (Smyth et al., 2017). Currently, limited research has been undertaken to understand the precipitants of stress within this growing conceptual framework. Existing work indicates a variety of stressors (i.e., stress precipitants) underpin the stress response via several mechanisms including domains and magnitudes of perceived threat (Almeida, Wethington, & Kessler, 2002).

This study will advance existing stress detection work by developing a richer understanding of the underlying causes of stress (i.e., stressors), to provide additional context and understanding that may subsequently be used for tailored intervention development. The computer science requirement for such work to be undertaken requires a richly labeled dataset, for which many proximal and distal benefits may be rendered. Although some limited datasets exist that have broad annotation of few stressors (Bari et al., 2020), they are useful only for the detection of conversation-related stressors. Further, they are not publicly available for the scientific community.

Currently, a dearth of technical infrastructure exists for mHealth metadata systems. The dataset arising from this study will be useful for computational and data scientists to continue to build infrastructure for future research of this type.

References

Almeida, D.M., Wethington, E., & Kessler R.C. (2002). The daily inventory of stressful events: An interview-based approach for measuring daily stressors. *Assessment 9*(1), 41-55.

Bari, R., Rahman, M.M., Saleheen, N., Parsons, M.B., Buder, E.H. and Kumar, S., (2020). Automated Detection of Stressful Conversations Using Wearable Physiological and Inertial Sensors. Proceedings of the ACM on Interactive, Mobile, Wearable and Ubiquitous Technologies, 4(4), pp.1-23.

Hovsepian, K., al'Absi, M., Ertin, E., Kamarck, T., & Kumar, S. (2015). cStress: Towards a gold standard for continuous stress assessment in the mobile environment. Paper presented at ACM UbiComp 2015. Retrieved from http://web0.cs.memphis.edu/~santosh/publications.html

Kumar, S., Abowd, G.D., Abraham, W.T., al'Absi, M., Beck, J.G., Chau, D.H., . . . Wetter, D.W. (2015). Center of Excellence for Mobile Sensor Data-to-Knowledge (MD2K). Journal of the American Medical Informatics Society. Retrieved from http://jamia.oxfordjournals.org/content/early/2015/07/01/jamia.ocv056

Saleheen, N., Ali, A.A., Hossain, S.M., Sarker, H., Chatterjee, S., Marlin, B., . . . Kumar S. (2015). *A multi-sensor approach for pinpointing the timing of first lapse in smoking cessation*. Paper presented at ACM UbiComp 2015. Retrieved from http://web0.cs.memphis.edu/~santosh/Papers/puffMarker.pdf

H. Sarker, M. Tyburski, M. Rahman, et. al., "Finding Significant Stress Episodes in a Discontinuous Time Series of Rapidly Varying Mobile Sensor Data," ACM CHI, pp. 4489-4501, 2016. Retrieved from http://www.cs.memphis.edu/~santosh/Papers/Stress-Intervention-CHI-2016.pdf

Smyth, J.M., Sliwinski, M.J., Zawadzki, M.J., Scott, S.B., Conroy, D.E., Lanza, S.T., Marcusson-Clavertz, D., . . . Almeida, D.M. (2017). Everyday stress response targets in the science of behavior change. *Behavior Research & Therapy 101*, 20-29.
Zhang, S., Rowlands, A.V., Murray, P., Hurst, T.L. (2012). Physical activity classification using the GENEA wrist-worn accelerometer. *Medicine & Science in Sports & Exercise, 44*(4), 742-748.

Possible contribution: Over the past decade, considerable progress has been made in developing algorithms for detecting stress episodes from sensor data. But, stress-triggered interventions are still non-specific to the source of stress, and, hence, have limited utility and uptake. Our research will help to address this limitation by advancing the understanding of how personal behaviors, environmental stimuli, and socio-environmental context (i.e., daily stressors) can cause, accentuate, or otherwise be associated with stress. This research will serve to objectively identify the "why" behind stress responses.

A paucity of research in this realm has been a major roadblock to crafting tailored stress interventions, which are currently static (e.g., encompassing a one-size-fits-all approach using biofeedback or mindfulness), and are unable to capture the dynamism of stress in people's lives. Ultimately, this research will help to find methods by which people can effectively manage their stress via better understanding of how other socio-environmental stimuli (daily stressors) are associated with stress.

A necessary component of this research study is developing the appropriate structure, and annotations for data of this type, e.g., for utility in secondary data analyses. This component will, in itself, yield meaningful, generalizable impact to research communities investigating data science, computer science, and big data.

*required

Methods and Procedures

a) Study design. Provide a summary statement of the design methodology used. For example, stating that the study is a randomized clinical trial using a double blind procedure with a placebo control. Another example would be a reanalysis of de-identified archival data.
b) Materials. Provide a concise description of all special equipment, instruments, or measures in this section. Also, label and attach copies of data collection tools at the end of this Initial Review Request.
c) Procedures. Provide a chronological description of the experience of being a participant in this study. For archival data, describe how the data is secured, stored, and used. Include the process by which consent will be obtained.
d) Indicate which procedures and treatments are associated with the present study and those which are not part of the study (i.e., pre-existing programs, interventions, or classroom exercises).

Study design: This observational study involves prospective data collection, transformation, analysis, retention, and sharing of mobile sensor and survey data collected across several phases. Our initial phase regards data collection from 100 participant completers for approximately (i.e., at least) 100 days. (Participants will be allowed to continue contributing data if they choose until the study concludes.)

Our goal is to recruit participants who are interested in monitoring their daily stress and stressors. We may also recruit from groups who identify as citizen scientists, i.e., individuals who have active desire to voluntarily contribute research data for the greater scientific good. For example, we specifically plan to recruit from the Open Humans research community. (Some of these participants are also a part of the related Personal Genomes Project research study.) We may also recruit from a general population of citizen scientists or otherwise those interested in self-monitoring via smartwatch technologies to reach the goal of 100 participant completers. The participants are to be geographically located within the United States of America. (More information regarding study populations is located in the appropriate, subsequent sections regarding human subjects.) Mobile sensor data will be collected and stored on a secure computational cluster located at the University of Memphis.

Materials: The proposed research that will occur at the University of Memphis will involve data that is collected from participants via the following materials:

- A smartwatch will be worn continuously on the participant's wrist during waking hours during the study period (except for situations in which the sensor may be submerged in water like bathing or swimming). This wrist may be the dominant or non-dominant wrist, depending on participant preference. Each of these devices includes passive sensing modalities akin to those available in commercially available activity trackers such as 3-axis accelerometers and 3-axis gyroscopes, and may include other sensors such as heart rate based on reflectance photoplethysmogram (PPG), UV light exposure, magnetometer, and a skin contact sensor. Data are collected from these sensors via wireless radio connection to the participant's own smartphone in real-time.
- Participants will use a dedicated study software application suite on their own smartphones and on the study-provided smartwatch for the collection of physiological and survey data. This study software has been developed by the MD2K Center of Excellence and prior versions of the software

has been used in tens of studies with well over 1,000 research participants.
The software collects the high-frequency mobile sensor data, performs computations in real-time to detect health states of interest (e.g., stress), collects user-initiated self-reports from participants, and prompts participants to complete surveys at specified times. The study software will prompt participants daily to reflect on their data, as collected by the mobile sensing platform. For example, participants will be asked to annotate periods of system-identified stress events and may annotate stressors that precipitated or co-occurred with the events. Participants may also self-report stressors or perceived stressful events to the system. The system may also query the participant during periods of low-quality sensor data, to obtain ground truth regarding cause (e.g., loose wear of the sensor). The study software will collect raw GPS traces to allow for modeling of location and geo-exposure with stress events and stressors. The study software may also collect non-identifiable usage statistics such as call usages (e.g., counts and duration of calls or messages), app usages (e.g., type of app and duration of usage), screen time on/off, and other phone sensor detections such as ambient noise detection. Data are collected wirelessly (e.g., via cellular data plan or WiFi) via a secure (HTTPS) connection to the back-end computational cluster housed at the University of Memphis. Data that are stored on the phone are secured in the same manner as other personal data secured on the smartphone device. The application suite may continue to be used until the study team terminates data collection and aggregation (some functionality may end at that point), or it may be easily removed (uninstalled) by users at any time. The application suite was developed via the NIH-funded Center of Excellence for Mobile Sensor Data to Knowledge (MD2K), and development has continued using other NIH and NSF-funded sponsored programs. The application suite is open source, and does not pose additional risk to smartphone use or users beyond commercially available activity tracking applications used every day: Additional technical information regarding the software is available at https://software.md2k.org.

Procedures:

This study will involve the collection of physiological and survey data as obtained from mobile wearable sensors worn by participants across the United States and recruited by the research team at the University of Memphis. These physiological data will ultimately be aggregated at the University of Memphis for sharing visualizations/data representations back with participants and broader sharing with the scientific community.

Participant Recruitment and Physiological Data Collection

Our goal is to enroll 100 research participant completers. These participants will all be adults who are located across the United States. Our focus is to recruit people who are interested in monitoring and sharing their patterns of stress (and the related stressors) from their daily life, both when they are stressed and not stressed as collected by the sensor platform and their annotations of the sensor data.

Prior to beginning the study, the study team will screen potential participants via an online form. Following successful screening, participants will be asked to complete a baseline questionnaire, e.g., via Qualtrics, for demographics and categories of daily stressors prevalent in their lives. Upon successful screening, participants will provide their email address, will be granted a unique, non-individually identifiable access code, and will be instructed how to download the dedicated study smartphone application via their respective official application store (e.g., App Store for iOS users or Play Store for Android users). We plan to recruit in batches of approximately 10 participants roughly biweekly to ensure adequate study coordination span-of-control. If we obtain oversubscription (i.e., more successfully screened prospective participants than a batch allows), we will select prospective participants to be granted the access code to continue with the enrollment process. This selection process may be random, or we may weight the selection based on demographics such as geography or occupation to help obtain a more representative sample of participants and their stressors. Participants not immediately selected will be moved to a subsequent batch to consider the enrollment process at that time. Once the application is installed and the access code validated, and digital informed consent will be obtained.

After agreeing to the study via informed consent, participants will be asked for additional contact information (e.g., mailing address). Participants will then be mailed one smartwatch via certified mail. Users will sync the smartwatch with their smartphone and install the MOODS app for collection of the physiological data. Once daily, the participants will be prompted to complete a survey and annotate their sensor data for the day. We will expect participants will spend approximately 5 minutes daily (or may spend more time if they desire to reflect on their data more extensively) identifying periods when stress was detected by the study software, and annotating stressors, precipitants, and/or any other reflections of the experience(s). Based on previous mHealth stress research of this type, we expect participants to have an average of 2-3 stress events/day, though this may be more or less depending on the participant. Participants will be asked to charge the smartwatch daily, using a provided charging cable. Participants may charge the device when convenient for them, including during sleep.

Each week, participants will receive visualizations via a dedicated hyperlink to their study-provided email. These weekly visualizations will display different representations of each individual user's data and/or aggregate (population-level) data. Participants will be encouraged to share feedback toward usefulness, utility, criticisms, and any other feedback.

Following the delivery of weekly visualizations, to help us answer and evaluate the specific goals of the study, we will also ask participants to complete a weekly questionnaire that includes: (1) a Stress Awareness Assessment to assess how participants' awareness of their stress and stressors may evolve or change throughout the study, (2) questions that evaluate participants' perceived impacts of the visualizations on their daily behaviors, (3) questions that evaluate the burden of the study procedures on participants, and (4) questions that evaluate data explanations and how those might improve the utility of participants' collected data.
These questionnaires will be repeated weekly until the end of the study. We expect the weekly questionnaires to take approximately 5-10 minutes.

Additionally, we will provide an opportunity to participants for a one-on-one exit interview at the end

of the study. This interview will be framed as an invitation for feedback, during which participants will have the opportunity to provide qualitative feedback to their overall experiences, benefits, problems, or any other observations they wish to share. The consent form will provide participants an opportunity to opt-out of either a synchronous (e.g., telephone), recorded interaction or asynchronous (e.g., email) opportunity. Participants who do not opt-out of the exit interview will be contacted toward the end of the study data collection period. If participants do not respond to the exit interview, we may follow up, but will make clear the exit interview is optional and not a requirement for their study completion.

The sensor and self-reported (e.g., questionnaire) data will be aggregated via the study software and securely synced to a secure computational cluster at the University of Memphis. (Described in the subsequent section.)

Physiological Data Aggregation, Computation, & Data Analysis

Study data from each participant will be collected via secure storage at the computational cluster managed by the MD2K Center of Excellence and located at the University of Memphis. Data security will be maintained using secure protocols during export from the smartphone (e.g., HTTPS), and during storage on the computational cluster using (1) a firewall that limits access to a whitelisted set of IPs/subnets, (2) 2048-bit SSH keys for authentication of individual access accounts, and (3) Memphis VPN access for those computers/individuals that do not fit into the set of whitelisted IP addresses. Data security will be provided by limited access accounts where each individual will explicitly be granted access only to the datasets for which they are authorized.

While data is being collected and after completion of the study, work will be conducted to identify the precipitants of stress episodes, characterization of stressors as related to physiological and environmental factors, and refinement of computational stress detection methods.

Data Sharing & Privacy

We plan to obtain data from participants in a coded manner and will provide segments of these data (except for raw GPS) publicly for the greater scientific community to advance computational science with an unprecedentedly rich (i.e., labeled) dataset, and in the interests of advancing citizen science. However, we plan to engage with the participants in a participatory manner: We plan to provide the participants meaningful visualizations collected from their study data for them to use in their citizen scientific interests and to inform our longitudinal data collection practices among a population of savvy, engaged citizen scientists. During the study period, participants will be able to use their mobile phone-based study software interface to explore their data elements. Participants will also receive a weekly email with a link to (non-identifiable) individual- and population-level visualizations, and will be encouraged to provide feedback to describe what visualizations are most useful or meaningful to them. Participants will be able to censor their stress events via the MOODS app. Participants are also provided with the ability to pause data collection in real-time via the study smartwatch interface.

We are offering these functions because, while a key research goal is to automatically and objectively identify stressors, we also want to know what constitutes the greatest burden of the data collection, what provides the greatest value, and what participants wish the platform provided, but didn't. Given the intentionality of public release of these data, we want to know participants' privacy concerns and how they ultimately desire to censor their collected data from public release.

Participants who want to further dialogue about the platform will also be able to communicate with the study team via email. Participant feedback may be shared in a de-identified or aggregate manner.

Participants will also be able to receive a copy of their study data at the end of the study if they request it. We know, and expect, that some participants will share their data with others in a similar manner that some of them have shared their genomic information, medical records, demographics, and real names. While we will share all released (i.e., publicly shared) data in a coded manner, we expect that some participants will share the data on or linked to their Open Humans, PGP, or other profiles, some of which are publicly accessible via the internet. Therefore, the key to re-identify those data will likely be made available by the participants themselves. Because of this, we are to be very explicit with our consenting process. Regardless of previous data sharing by this group, we will use codes for this study that do not link back to their Open Humans or PGP identifiers, in case any participants do not wish to publicly identify their data as it relates to this study. Moreover, PGP participants have undergone and continue to undergo annual consenting processes. For participants who are not recruited from the Open Humans or PGP study populations, we will be clear that any further disclosures made by the participants may cause their research data to become identified.

Because of the particularly sensitive nature of raw time-stamped GPS data, we will only publicly share geolocation data that has been coded into location clusters, also known as points of interest (e.g., "home", "work", "school") -- otherwise converted into de-identified variables of interest. However, we will provide their own raw GPS traces (i.e., latitude, longitude, and related location metadata) to participants who want them. Even among participants who may be recruited more generally (i.e., as members of the general public, or members of Open Humans or PGP who may limit access to their data), we expect to recruit individuals with high interest in self-monitoring via mobile sensing technologies. We will make clear to participants that any data they elect to share, and concomitant risk, is up to their judgement.

Attachments: Instruments and Measures

Brief Sleep Survey.pdf

MOODS adapted Brief Health Survey.pdf

MOODS exit questionnaire.docx MOODS

stressor list.docx

Daily_Review_of_Stress_Data.docx

MOODS_Survey_Questions.docx

Exit_Interview_(Oral_Email).docx

Weekly visualizations email.docx

Secondary analysis of existing data

10

The specific information is necessary when identifiable data about human subjects will be obtained. Data are identifiable if they include direct or indirect identifiers such as name, email address, UID Number, race, gender, nationality, age etc.
a) List source of the data and an explanation of why the data were originally collected.
b) Describe in detail the data you plan to access and analyze.
c) Indicate the requirements of the data supplier and how access to the data will be granted or obtained. If access to the data is governed by a data use agreement, provide a copy of the agreement.
d) Describe procedures that will protect data you are given access.

This study is designed for primary data collection to take place to perform the predictive stressor/stress episode research to take place. This study is also designed to provide ongoing data utility for further secondary analyses, given the publicly available nature of the dataset to be released at the conclusion of the study, and the interest of the participants to conduct further citizen science on their own data.

One of the necessary components to execute this study will be to discover the appropriate data structures, metadata, and annotations for data of this type, e.g., for utility in secondary data analyses. This outcome will, in itself, lend utility to future uses of this dataset and datasets like this.

Data information: Data Use Agreement, Data Sharing Agreement, Variables List etc.

*required

Investigator Qualifications

a) Describe the research team's qualifications and experience pertinent to conducting this research project. **This description must address and include information about the lead investigator and, if the lead investigator is a student, the faculty advisor as well.**

b) If physical or psychological assessments are being administered who will administer the assessment and score the results and what are their qualifications for doing so? Is the training in human subject protection of those administering assessments adequate?

The lead investigator for the study at the University of Memphis, Santosh Kumar, PhD, serves as the director and principal investigator (PI) for the MD2K Center of Excellence, leading the forefront of research on mobile sensors and mobile health (mHealth) for over 14 years. The lead investigator has experience leading several transdisciplinary projects spread across multiple universities and involving an array of investigators from diverse fields such as psychology, engineering, computer science, and mathematics. His work has been sponsored by large grants from both NIH and NSF (including R01, U01, U54, and P41 from NIH). In his first mHealth project called AutoSense, sponsored by the National Institutes of Health (NIH) in 2007, under its Genes Environment & Health Initiative (GEI), his team developed a wearable sensor suite, called AutoSense, for collecting physiological measurements from the natural environment. Subsequently, in the FieldStream project, sponsored by the National Science Foundation (NSF) in 2009, his team developed novel machine learning models of various human behaviors and a software framework on the smartphone to infer various psychological, behavioral, and social contexts in real-time. MD2K Center of Excellence, originally funded by NIH in 2014, has developed innovative tools and open-source software to make it easier to collect, integrate, manage, visualize, analyze and interpret health related data generated by mobile and wearable sensors. The goal of these big data solutions is to reliably quantify physical, biological, behavioral, social, and environmental factors that contribute to health and disease risk. MD2K's current software platforms and its predecessors have been used in more than 20 studies across 11 states, involving over 1,000 participants to investigate stress, pain, smoking, overeating, heart failure, oral hygiene, work performance, and cocaine use. Hundreds of terabytes of sensor data collected by MD2K software are hosted at MD2K servers and has been used to discover novel mHealth biomarkers such as stress, conversation, smoking, craving, cocaine use, brushing, and flossing, and sensor-triggered interventions.

In addition to direct experience with leading transdisciplinary research in mobile sensor projects, Dr. Kumar has led national efforts to advance the field of mobile health (mHealth). He has chaired several national meetings on "mHealth" organized by NIH and NSF. He mentors faculty members across the country in mobile health as part of the annual mHealth Summer Institutes. Dr. Kumar has advised the NIH Director on advancing mHealth, given a talk on the future of biosensors at the White House, and served on the advisory board of NIH PRISMS program. His works have been published in renowned international venues, and been cited over 8,000 times (according to Google Scholar).

Dr. Kumar and his study staff have been trained and remain currently certified in human subjects training via the CITI Program. Moreover, Dr. Kumar has on his staff a Research Director (Shahin Alan Samiei) who is responsible for ensuring that all human subjects research is conducted within both the letter and the spirit of regulations that govern the protection of the rights of human subjects. This team has conducted extensive research studies, including primary data collection, interaction with living human subjects, and tiered consenting processes with respect to data sharing.

*required

Human Subjects

a) Characteristics. Describe the characteristics of the participant population. Include the age range(s), gender, ethnicity, health status, any physical, mental, cognitive or emotional limitations, and any other relevant variables.
b) Vulnerable Populations. Indicate if subjects include students, prisoners, pregnant women or any other class of subjects that might be especially vulnerable and require special consideration.
c) Pre-existing relationship to subject pool. If subjects are students, describe the relationship between students and researcher. If there is a pre-existing relationship between the researcher and the subject pool, please describe that relationship in detail.
d) Selection. Describe criteria for inclusion and exclusion of subjects in the study. Provide a detailed explanation for each exclusion and inclusion criterion.
e) Justification for the proposed sample size. This number helps reviewers understand the expected sample size. Please explain why this number was chosen for your sample size. Any increases to sample size require a modification to the study.

a. Characteristics

Participants will consist of 100 generally healthy volunteer completers who will be recruited virtually/remotely. These participants will be any willing volunteer, who meet the inclusion/exclusion criteria, who are interested in monitoring their stress and stressors via the study-provided smartwatch. We may also recruit via established citizen science groups, e.g., in collaboration with the Open Humans project (https://www.openhumans.org/about/) and Personal Genomes Project (www.personalgenomes.org). The Open Humans project allows participants to upload, store, and connect personal data to various research projects. Participants are allowed to restrict or freely donate their data to their preference. The PGP was founded at Harvard in 2005 for collaboration on the development and evaluation of personal genomic technologies and participatory practices at increasing scales. To date, the PGP has collected participant genome data on over 4,700 users. Similarly to the Open Humans project, some participants share their data in restricted ways, and others share their data more broadly: Over 200 of these users have elected to make their genome data completely public, and some have linked their profile pages to medical records (including lab test results, injuries, vaccination records, etc.) and demographic data (e.g., age, sex, gender, geographic location, etc.). (Information on the PGP informed consent process is available here: https://my.pgp-hms.org/static/PGP_Consent_2015-05-05_online_stamped.pdf.)

Participants will be recruited on a rolling basis. Our goal is to obtain 100 participants who complete the minimum duration of the study (100 days) by the end of the study. Based on previous stressor research (Almeida et al., 2002), we anticipate this will yield a sufficient number of labeled stressor events for modeling purposes. We anticipate a high enrollment rate and low drop-out rate after the screening and consent process, because Open Humans, PGP members, and self-identified citizen scientists are self-selected to be highly interested in self-monitoring and citizen science.

b. Vulnerable Populations

No vulnerable populations as defined in 45 CFR 46 are planned to be recruited for this study. The enrollment criteria include generally healthy adult volunteers who are able to provide informed consent.

c. Pre-existing relationship to subject pool

There are no pre-existing relationships between the study team to the subject pool.

d. Subject Selection

Participants will be invited to initiate contact with the study team via recruitment methods described in Section 7. Potential subjects will be prompted to answer questions online confirming eligibility criteria. Following screening, participants will be prompted to complete the electronic informed consent process and certify consent to participate in the study.

Inclusion criteria include generally healthy; lives in the United States with no intention of moving outside of the country during the study period; adult (age of 18 years, 19 years if Alabama or Nebraska resident, or 21 years if Mississippi resident), willing to wear a study-provided smartwatch for all waking hours (except when charging, bathing, or swimming) during the 100-day study period; have smartphone compatible with the data collection application suite, and adequate data connection (Wi-Fi access or sufficient cellular data plan) for communication with the University of Memphis servers; indication of experiencing daily stressors of interest, as listed in screening form. Exclusion criteria include residence outside of the United States; inability to read English; unable or unwilling to participate in study procedures. Participants who do not participate in the study for one continuous week and who do not respond to follow up communications from the study team will be considered withdrawn from the study.

e. Anticipated Number of Subjects

We expect that 200 subjects will be enrolled, with the goal of obtaining 100 completers. Given that our study population are self-identified citizen scientists or are otherwise personally invested in self-monitoring, we do not expect attrition to be very high. However, we recognize the longitudinal request of the study, and are budgeting for an appreciation of participants who may wish to withdraw at any time.

*required

Recruitment

Describe how subjects will be identified and recruited.
Provide detailed description and examples, where relevant, of any material to be presented to potential participants prior to their receipt of the informed consent/assent documents.

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Recruitment material scripts and flyers may be disseminated via web postings (e.g., blog, forum, or social media), or via traditional posting mechanisms (e.g., community bulletin boards and email lists). We may also reach out to collaborating projects (e.g., Open Humans) to leverage their connections with willing subject pools: The collaborating projects will make available our recruitment materials to their study populations, and those populations will have the voluntary opportunity to seek more information and participate if willing. Study personnel will send an email describing the study and requesting participation to the projects' staff. The staff will review the recruitment materials and then forward it via their communication channels (e.g., email list, website). Prospective participants who are interested will be able to follow the instructions within the recruitment materials to reach the online screening process.

Participants who meet the enrollment criteria will then submit their email address to the study team. Participants will then be selected by the study team randomly or weighted based on demographic characteristics to help obtain a representative sample. The email address will be used to generate an invitation-only access to the study app via the respective Android or iOS app store (based on participant selection) to download the invite-only study app. The participant will then complete the informed consent process. If the participant agrees to the study procedures via completion of the informed consent, they will then submit further contact information to be shipped the study-provided smartwatch and begin study enrollment. If prospective participants do not consent to the informed consent processes, we can offer them the opportunity to retain their email addresses for future studies, or to remove their email addresses from our records. Once the study-provided smartwatch is received by the participant, final instructions will be provided to pair (connect) the smartwatch with their smartphone and begin the data collection procedures.

Recruitment materials: are attached to this review application.

Recruitment Materials

Attach advertisements, postings on social media, posters, scripts for radio/TV, other electronic ads, scripts for verbal recruitment, copies of email recruitments and any text that will be provided to potential participants. It should be clear in all recruitment materials that you are conducting research. See Sample Recruitment flyer on IRB website.

MOODS flyer tracked 20110312.docx Sample documents: sample_recruitment_flyer.doc

MOODS forum & blog post 20210312.docx

MOODS Recruitment email 20210312.docx

*required

Subject Compensation

a) Describe any economic or other incentives for participation including reimbursement for time and travel.
b) If study participation requires subject to complete multiple sessions, compensation must be pro-rated over
the course of the study. (Example: In a study where subjects are compensated $50 per session, Tom completes only two sessions, then he should be compensated $100 for his participation)
c) If the study incentive involves earning course credit, list alternative ways to earn the same credit.

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Participants will be sent weekly visualizations of their stress and stressor patterns described in the Procedures section: These visualizations will display representations of participants' own data . In addition, participants will have the option to receive data exports for their own analyses. These data may allow participants to reflect on their own stress patterns and glean insights on how to better manage their stress. Participants may also be able to use this platform to observe the impact of any stress management strategy they employ on their daily stress levels. Because of the richness of this dataset and the intrinsic curiosity of participants to engage in research of this type, we expect this bidirectional participatory relationship will be commensurate with the burden of wearing the sensors and responding to questionnaires. Moreover, participants who complete the study will be allowed to keep the smartwatch that is provided for this study (approximate value: $112). Participants can use the smartwatch and study software to continue collecting data about themselves, if desired. For participants who do not opt to keep the smartwatch and want to send the smartwatch back, they will be provided with a prepaid return shipping label.

We will define successful completion of the study via the following five criteria:

1. Wear the sensors for at least 8 hours per day, for a total of at least 800 hours over the 100 days.
2. Complete the daily review of stress events at least 5 times per week.
3. Complete at least 10 of the 14 weekly assessments.

Participants completing the study as outlined above will get to keep the smartwatch. Participants who do not meet all of the criteria as listed above will be asked to mail back the sensor via a pre-paid mailing package. However, given the effort participants may have put into the study and the assessment of benefit-to-cost of retrieving the equipment, we will not actively pursue retrieval of the study sensor if a non-completer does not wish to comply with returning the sensor.

Risk Benefit Analysis

*required

Potential Risks

a) Describe all potential risks: physical, psychological, social, legal or other associated with each procedure. Assess the probability, severity, potential duration and reversibility of each risk.
b) Identify those risks that are minimal and those which are more than minimal.
c) Describe the procedures used to minimize any potential risks.

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- This study's data collection procedures do not involve any risks beyond those ordinarily encountered in daily life or in the performance of routine tests.
- Participants may experience some burden from wearing the smartwatch. Previous studies with wristband sensors have indicated that after a brief adjustment period, the majority of the participants adjusted to wearing the bands and did not find them to be intrusive or restraining. We expect that the smartwatches, which have precedent of prior use in a research study or have otherwise been designed for everyday wear, will elicit similar acceptability among the participants in this study. All sensors in the smartwatches have been in common use for several years, and pose minimal risk to participants.
- We will publicly share coded data from this dataset that we will not link back to participants. However, participants may decide to share these data in a manner that identifies them. The risks of these identifiable disclosures may include unforeseen risks. This will be communicated to research participants.
- Location data (GPS) collected from the participants has the risk of independently identifying the participant by depicting his/her exact location at a given time during the study. GPS data will depict every location the participant has been while in the study, which may be potentially embarrassing if revealed. Hence, we will geocode (de-identify) these data to remove any identifiability before we publicly share the dataset. Because we need the raw data for environmental context modeling of stressors, the study team will retain these raw data, and they will be kept secure using best practices in data security. Moreover, access to these data will be restricted to authorized investigators and study staff who have IRB approval, have completed training in human subjects protection, and have agreed to uphold the privacy of participants in this study. However, participants will be provided these raw data if they request them. Participants will be informed that, if they share their data in an identifiable manner, or share their raw GPS data, they are relinquishing privacy in a similar, intimate manner as when they release their medical records.
- It is unlikely that the questionnaires or other data collection or sharing procedures will lead to any legal, social, or psychological problems in and of themselves. Similar measures have been tested in a variety of research programs and no problems have been reported due to their use. Moreover, we will not share participants' individual responses in a manner that could be used to identify them directly. Participants will be clearly informed that they are always free to refuse to answer questions that may be upsetting, should this unlikely situation arise. Participants will also be informed that they may withdraw participation at any time with no

consequences to other research participation or services to which they would otherwise be entitled. Participants will be informed that the scope of their own, identifiable, sharing may yield unforeseen consequences to privacy, in similar language to which they are informed via their participation in the Open Humans project and PGP. The same, intensive level of informed consent will be provided to all participants, including any members of the general public who participate in this study.

*required

Potential Benefits

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a) Describe the direct potential benefits to the subject. If there are none, this should be so stated.
b) Describe the potential societal benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society.

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There is no assured direct benefit to the study participants. This study has the potential to engender greater awareness of health by way of participants' interacting with the application and their collected data. As such, participants may experience (but are not guaranteed) health benefits from increased awareness of their stress and precipitants of stress. Participants may also be able to observe the impact of any stress reduction mechanisms (e.g., their own intervention techniques or participation in other stress reduction interventions like third-party applications or meditation) on themselves. Participants may also gain greater personal insights by comparing their study data to aggregate study sample data, when released.

Results from this study may benefit society by contributing to the body of knowledge regarding stress, stress detection, computer science, and big data science. This study will be seminal in the development of techniques to automatically identify specific stressors from sensor data. Work of this type may serve as foundational to future research which explores the remarkably complex interactions between stress, daily behaviors, and environmental factors. We expect the dataset to be garnered from this study will be unprecedented in multiple scientific domains.

*required

Differential Evaluation of Risks and Benefits

Justify the research study based on your evaluation of the risk/benefit assessment. When composing this section, imagine you are standing in front of a panel of researchers who are all skeptical about your research. Your task is to reassure them that the benefits of your research outweigh the risks.

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The potential benefits of this study outweigh the potential risks to study participants. This study will provide data that will give us a fundamental understanding of the interactions of stress, stressors, physiology, and environment. Moreover, this study may help demonstrate the technical ability and garner novel insights into the objective identification of stressors via mobile sensing technology. Risks to participants are minimal, and predominantly surround subjects' agency of privacy. In that vein, study participants are being provided informed consent with the intentionality and mindfulness of their future contribution to the body of data

science, predictive analytics, and physiological/psychological science. While the subjects for this study will be particular groups of individuals – e.g., subjects who are interested in self-monitoring – the investigators of this study have carefully considered the risks to participants and have made concerted and careful efforts to both minimize the risks and maximize the benefits to study participants and to society as a whole. We give willing participants the agency to identify themselves (or not) in this dataset, just as they do with the rest of their research participation. All participants who participate in this study will be provided the informed consent to the sharing of their data, and have the agency to keep their study participation confidential. As such, this study is aligned with both the spirit and the letter of extant regulations governing the protection of human subjects in research studies.

*required

Privacy

The research proposal should outline strategies to protect privacy, including how the investigator will access participant information.
In developing strategies for the protection of subjects' privacy, consideration should be given to:

- The methods used to identify and contact potential subjects.
- The settings in which an individual will be interacting with an investigator.
- The appropriateness of all personnel present for research activities.
- The methods used to obtain information about subjects.
- The nature of the requested information.
- Information that is obtained about individuals other than the target subjects, and whether such individuals meet the regulatory definition of human subject (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines.
- How to access the minimum amount of information necessary to complete the study.

●Participants' contact information will be linked to their study data via a code. The key to this code will be available only to the necessary research staff at the University of Memphis to conduct the research, and will be secured separately from the rest of the study data that is transmitted to the MD2K Center of Excellence at the University of Memphis. Participant contact information that is used for feedback sharing will only be used among the necessary research staff at the University of Memphis to complete participant interaction functions.
●Participants will be informed of their rights to terminate their participation in the study at any time.
●All personnel that will be present for the research activities will be essential personnel in the conduct of this research. All personnel who will virtually interact with participants, and all personnel

who interact with the participants' data at the University of Memphis are trained in human subjects research. These personnel include Dr. Santosh Kumar, his students, and his study staff at the University of Memphis.

- All information that is collected from the participants will be the minimum necessary to conduct the research. Study participants will be informed that research data collected about them, including identifiable GPS (location) traces, will be stored at the University of Memphis until they are no longer useful. It is estimated that the data will possibly be useful for 10 years, but that the data may be useful and may continue to be retained much longer than that (i.e., indefinitely).
- Study participants will be informed that this research is conducted as a part of a collaborative, multi-institutional research team (see section 14). Study participants will be informed that data that may identify them (specifically, GPS) may be shared from the MD2K computational cluster, housed at the University of Memphis, with other researchers at other institutions who are a part of research collaborations, if those researchers have a legitimate, IRB-approved question regarding these data. Participants will also be informed that their research data that does not include GPS or other direct identifiers will be shared publicly (e.g., via the Internet).
- Participants will be informed that they will need to install the commercially available WearOS application in order to integrate the study smartwatch with their smartphones. Participants will be informed that they must agree to the Google Privacy Policy and Terms of Use for the WearOS application. Participants will be informed that they can restrict, delete, and manage any data shared with Google as a part of this study. The risks of using this application are similar to the use of commercially available (i.e., Play Store or Apple Store) apps that people use every day, and risks are no greater than typically encountered in daily life.
- Participants in the study will be able to view aggregate data from other participants. No identifiable data from one participant will be shared with another participant.
- Data will be de-identified to the maximum extent possible to perform the necessary research. However, geo-spatial (GPS) data could independently identify participants. Therefore, location data will be stored separately and only used by trained, approved investigators with a legitimate scientific interest who have IRB approval and have agreed to maintain confidentiality of the data and uphold the privacy of study participants. These GPS data may be provided back to the participant upon request, and participants will be informed that their sharing/self-identification of these data may have unforeseen proximal or distal risks.

*required

Confidentiality

The research proposal should outline in detail what variables of identifiable data will be handled, the strategies to maintain confidentiality of identifiable data, including controls on storage, handling, sharing of data as well as eventual destruction of identifiable data including signed consent forms.

NOTE: If using an online survey like Qualtrics, Survey Monkey, etc., change settings to

Anonymize Responses so IP addresses will not be collected. The Qualtrics default is to collect IP address and GPS coordinates of respondents. By setting the survey to Anonymized Responses the investigator will not be collecting this identifiable information. Include this language in the Confidentiality, Methods/Procedures, and in any other necessary sections/documents noting that the investigators will set Qualtrics to Anonymize Responses.

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- Only trained investigators and their research staff conducting the study will have access to contact information or other identifiable human subjects data. Other investigators who may have access to human subjects data are collaborating institutions that comprise the MD2K Center, including its mProv sponsored program collaboration (see Section 15) and are detailed in the following point:
- Participants of this research study will be informed of the collaborative nature of the MD2K Center, which includes the following procedures: (1) the secure transmission of identifiable study data to the MD2K Center computational cluster at the University of Memphis, (2) that, with IRB approval, identifiable human subjects data (e.g., GPS) may be shared from the computational cluster with other mHealth researchers with collaborating institutions, and (3) that all investigators must agree to maintain the confidentiality of participants' data.
- All collected study data will first be aggregated on the MD2K computational cluster at the University of Memphis. Following necessary computations and analysis, coded data will be publicly shared to the open public for further research utility. (Details regarding the data sharing are detailed in the study procedures and privacy sections).
- Study participants will be informed that research data collected about them, including identifiable GPS (location) traces, will be stored at the University of Memphis until they are no longer useful. It is estimated that the data will possibly be useful for 10 years, but that the data may be useful and may continue to be retained much longer than that.
- Study participants will be informed that this research is conducted as a part of the collaborative research performed by the MD2K Center of Excellence (see section 14). Study participants will be informed that data that may identify them (specifically, GPS) may be shared with other researchers at other institutions who are a part of this collaboration (see section 14), if those researchers have an IRB-approved question regarding these data. These investigators must provide documentation of Institutional Review Board approval and must agree to maintain the confidentiality of participants' data before data from this study will be shared with them.
- Participants will also be informed that their research data that does not include GPS or other direct identifiers will be shared publicly. Participants will be informed that their own data sharing decisions (e.g., linking coded data collected from this study to their own identifiable information, such as a PGP page containing first and last name), may well identify them to all data collected from them during this study. Participants will be provided informed consent to the foreseen risks and possibility of unforeseen risks regarding the nature of their extant data sharing. Our informed consent process mirrors this process and leaves the agency of identifiability to the informed participant(s).

*required

Collaboration, Engagement & Sponsor Relationships

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a) Describe all collaborative relationships necessary to complete your research. Include letters of support from the collaborator(s). This letter must come from a person with director-level authority within the collaborating institution. When the collaborator has an Institutional Review Board, please include a copy of the IRB application sent to collaborating institution.

b) Indicate in your study when U of M IRB approval must be issued before the collaborator will commit to the study.

c) Specify what data will be provided to the collaborator(s) and sponsor(s).

This research is being conducted under the collaborative auspices of the mHealth Center for Discovery, Optimization, and Translation of Temporally-Precise Interventions (mDOT), an evolution from the Mobile Data-to-Knowledge (MD2K) Center of Excellence, a national Big Data-to-Knowledge (BD2K) Center of Excellence funded by the National Institutes of Health as part of its BD2K initiative. This study is also working within the mProv project of the National Science Foundation. The University of Memphis IRB will be the IRB of record for this study. Any deviations or unanticipated or adverse events will be reported to the IRB.

Collaboration Attachments

Letters of support, IRB approvals / protocols from collaborating institutions

Proposal

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If your study is sponsored, please insert or attach a copy of the funded proposal under this section.

This study is being sponsored by the National Science Foundation to advance data science utility to the scientific community via sponsored program “CIF21 DIBBs: EI: mProv: Provence-Based Data Analytics Cyberinfrastructure for High-frequency Mobile Sensor Data” (Grant number 1640813). If required, copies of the grant proposals are available from the Office of Sponsored Programs.

Full Board and **Expedited** review-categorized research require informed consent for human subjects to participate in research. Such consent must be given by the subject and parent/guardian if the subject is under the age of eighteen (18) years. Voluntary and fully informed consent must be obtained and documented in writing unless a waiver is requested and granted.

Also, templates/guidelines for Informed Consent, Parental Consent, and Children's Assent forms are available on the IRB website.

EXEMPT review-categorized research also requires obtaining voluntary consent to participate. This consent will provide subjects with pertinent information such as stating that the activity involves research and the University of Memphis has approved the research. Also, as is appropriate, include information such as contact for investigators, description of the procedures, risks and benefits, and IRB contact information.

WAIVERS:

WAIVER OF DOCUMENTATION OF INFORMED CONSENT
45 CFR 46.117(c)
The Institutional Review Board (IRB) may consider waiving the requirement for obtaining documentation of informed consent if the following conditions are met. To request a waiver, justification for the waiver should be included in the IRB submission and should address each of the criteria listed below.

1. IRB may waive requirement to obtain a signed consent form for some or all of subjects if:
a. the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality; each subject must be asked whether subject wants documentation;
OR
b. the research presents no more than minimal risk and involves no procedures for which written consent is normally
required.

2. In cases where documentation is waived, the IRB may require investigator to provide subjects with written statement regarding the research.

[Note that 1a above is not included in FDA. 1b is included in FDA and HHS regulations 21 CFR 56.109(c)]

WAIVER OF INFORMED CONSENT*
THESE CRITERIA DO NOT APPLY IF THE STUDY IS FDA REGULATED**
45 CFR 46.116 [d]

The Institutional Review Board (IRB) may consider waiving the requirement for obtaining informed consent if all of the following conditions are met. To request a waiver, justification for the waiver should be included in the IRB submission and should address each of the criteria listed below.

1. THE RESEARCH INVOLVES MINIMAL RISK TO SUBJECTS
This condition is satisfied if either the likelihood or the magnitude of harm/discomfort is no greater than what the subjects would ordinarily encounter in daily life or during routine clinical care.

2. THE WAIVER OR ALTERATION WILL NOT ADVERSELY AFFECT THE RIGHTS AND WELFARE OF THE SUBJECTS
The IRB will assess whether subjects' rights, such as the "right to privacy", would be violated if the consent were waived. *For example, in the case of "right to privacy", the IRB will consider the safeguards for minimizing the potential invasion of privacy and will consider the potential benefits of participation.*

3. THE RESEARCH COULD NOT PRACTICABLY BE CARRIED OUT WITHOUT THE WAIVER;
AND
For example, obtaining informed consent would not be practicable if the investigator will have no direct contact with subjects and will not know their identities.

4. WHENEVER APPROPRIATE, THE SUBJECTS WILL BE PROVIDED WITH ADDITIONAL PERTINENT INFORMATION AFTER THEY HAVE PARTICIPATED IN THE STUDY
In social science research involving deception, it is common practice to debrief the subjects at the conclusion of the study. In other studies, however, it would not be appropriate to require debriefing. For example, if the research proposed collection of tissue without identifiers, it would not be possible for the investigator to provide additional information since the identities of the subjects would be unknown.

** To conduct research involving deception or passive consent procedures, these criteria must be met.*
*** Waiver of Consent in FDA regulated studies is permissible only in life-threatening situations or acute care research if specific FDA mandated requirements are met.*

Even if all of the above conditions are met, the IRB is authorized to require an investigator to obtain informed consent. For example, the IRB may determine that the knowledge being sought is not important enough to justify the use of unaware subjects.

Consent Documents

Attach Consent, Assent, Parental/Guardian permission, Waiver requests (Waiver of written documentation of informed consent, Wavier of informed consent)
MOODS consent 20210513 tracked.docx

*required

Consent statement (for exempt research), or waiver requests can go here

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If you have nothing to add here, please type n/a.
Electronic informed consent will be obtained by the research team at the University of Memphis, supervised by PI Dr. Santosh Kumar. Participants will be given the option to download or otherwise obtain a copy of their consent document for their own records.

Additional questions or concerns can be addressed to either irb@memphis.edu or by calling (901) 678-2705.

Any additional attachments can be added below:

Additional Attachments

Section 6 Investigator Contingency Response

When submitting your revisions to a protocol, inform the IRB how you addressed each of the contingencies for the previous version of the submission. Copy and paste the last issued contingency list in a Word document and include your response and related section/question directly underneath each respective contingency.

This document can be attached as an MS Word or a PDF file. You can also copy and paste your contingency response in the text box. See sample document below.

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*required

Add or attach your completed **Investigator Contingency Response** document. If you have nothing to add in the text box below, please type **"N/A"**.

Copy and paste document content here:

N/A

Or attach document here:

Sample documents: Example - Investigator Contingency Response.docx