Study title: ***A prospective, community-based observational study for creating a comprehensible electronic health record (EHR) database using wearable devices in African American cohort***

Researcher's: Dr. Liles, Ph.D., and Dr. Pawar, Ph.D., Department of Computer Science.

Purpose of this study: The study will collect health data of 30 African Americans in 6 weeks, each week 30 participants will be asked to wear the Withing's Smart Watch for 7 days. To achieve basic completion in phase 2, participants will be asked to wear their watches for 24h per day; obtain one sets of Electrocardiogram and oxygen saturation measurements every day at 12PM, other variables including heart rate, blood pressure, guided breathing exercises, amount of calories burnt, sleep hours and patterns, work-out in terms of steps, floors climbed and miles walked would be recorded automatically.

Possible benefits: The watch will continuously collect health data (i.e., heart rate, sleep cycles, physical activity, etc.) on participants which will then be utilized for understanding correlations between recorded variables and race specific health outcomes.

Data storage: The watch collected data is recorded in Withings Health mate software installed on Claflin's apple ipad, these recordings will be exported in a CSV file and stored in a secured password encrypted Claflin computer.

Recruitment and data collection timeline:

07/02/2022: Institutional Board Review (IRB) committee approved the study (Supplementary file 1).

07/18/2022: Recruitment email was sent through Claflin communications to faculty and staff for participating this study. Supplementary file 2 is the flyer used for recruitment.

07/19/2022: 14 subjects responded positively and showed their interest in participation.

07/20/2022: PI met all 14 subjects at their on-campus office location to explain the instructions (Supplementary file 3), handover the watch and get a signed consent form from the participants (Supplementary file 4). Following is the recorded heath data for 14 active participants.

The participant's name is deidentified (all identifying information removed) for privacy protection and has been numbered from 1-14 according to IRB instructions.

08/01/2022: A participant individual follow-up will be conducted to transfer the data from their watches to Claflin's computer for further analysis. Any participants with issues in data recording will require another round of re-recording for week.

08/02/2022: A sensitivity analyses will be performed to evaluate results by wear time, comparing thresholds of 8 hours, 12 hours, and 16 hours. Heart rate, blood pressure, step count, and walking and running distance will be collected from participants' watches. Data will be evaluated for normality, using histograms, and summarized as mean (SD) or median (IQR) for continuous variables and count (%) for categorical variables. Physiological and activity data across groups will be compared using a student's *t* test or an ANOVA, as appropriate. Watch and mobile phone-based activity measurements will be compared using a paired *t* test. Any found medical conditions as defined by ICD-9-CM and ICD-10 codes and recorded in the EHR will be extracted from enrolment. All statistical analyses will be done in R, version 4.2.0. A R shiny app will be deployed to do data sharing publicly from GitHub account (https://github.com/Claflin-SMART-HOME).

Appendix:

Supplementary file 1: IRB Protocol Summary_Liles_Pawar.docx
Supplementary file 2: Flyer.pptx

Supplementary file 3: Data-Recording-Instructions

Supplementary file 4: Consent-Form.docx