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1. Describe your research idea that would further an understanding of neurobiology as it relates to SUD and that is intended to be the basis for a successful start-up. (1 page)

Retailers often make predictions about your shopping habits and needs based on previous purchases. Why can't that same data that knows with high probability that you are going to buy Nike shoes also know when you need proactive support?

For individuals with substance use disorder, the propensity for returning to drug use (relapsing) is high. Historically, tools to fight addiction have been limited and retrospective. By the time a traditional intervention occurs, people are often already reusing. Relapses lead to a costly downward spiral - committing crimes, getting rearrested, being hospitalized, overdosing, and/or dying. Recent advances in wearable sensors, smartphones and artificial intelligence have created an unprecedented opportunity to produce positive health outcomes by predicting and preventing relapses and overdoses. The first step in this new era of proactive relapse prevention is to identify and measure digital biomarkers associated with relapse, and to implement a predictive model to achieve just-in-time intervention.

Behaivior is developing a relapse prevention platform that will consider a combination of physiological sensor data from wearable devices in combination with smartphone usage data, location data and reports from people in a support network to identify and detect relapse triggers in real-time. The first use case is opioid addiction.

Our solution will use advanced wearable devices (similar to FitBits) and pattern-detection machine learning algorithms to help people maintain sobriety. A critical component in preventing relapse is identifying the specific external and internal features that trigger (i.e. initiate) a relapse. External triggers are the people, places, or things that increase the likelihood of relapse; internal triggers are the bodily and emotional states that make relapse more probable. Some research to date has detected the physiology of drug use (Carreiro 2015, 2016, Kennedy, 2015). However, no research to date has used physiological sensor data analysis to identify relapse triggers in real-time, and thereby provide interventions to avert relapse when those triggers and craving/obsession states are detected. The recent literature calls for real-time interventions:

"Future studies should focus on utilization of biosensors to gauge response to behavioral therapy, to evaluate opioid tolerance and narcotic seeking behaviors, and to integrate with mobile technology platforms to deliver real-time interventions." - Journal of Medical Toxicology, 2016

Our proposed solution involves generating predictive models that will be trained at the population level and refined at the individual level.

2. Convince the challenge reviewers of your technical competence as a biomedical scientist. Be brief, selective and persuasive. Do not use the NIH Bibliographic Sketch format. (0.5 page)

For more than 15 years, Anind's research has focused on using sensors to understand human behavior and adapt systems to that behavior. This includes, in particular, work in providing support and adaptations for the self-management of acute and chronic diseases, and physical activity, including addictive behavior. Anind has spent considerable effort exploring the use of mobile technology and sensors for the purpose of collecting and providing information to patients and clinicians and detecting and predicting health behaviors of interest.

Jeremy's studies in the Bioethics program at the University of Pittsburgh have given him a background in the social science of medicine. He has continued to learn more about the medical field by becoming a subject matter expert on sleep apnea, postpartum and perinatal depression, and diabetes in the Jewish Healthcare Foundation health innovation fellowships he has completed. Jeremy led a proposal for screening and treatment advances for perinatal and postpartum depression, influencing the Jewish Healthcare Foundation's investment of \$150,000 in a new Allegheny Health Network service model for postpartum depression.

Through these fellowships Jeremy demonstrated many leadership skills and expertise in the health field by organizing numerous groups of health professionals across a number of important projects. Jeremy has been repeatedly invited to speak about his experiences, and invited to become a member of the Health Activist Network Advisory Group, to help the nonprofit Pittsburgh Regional Health Initiative effectively design, launch, and grow a Health Activist Network, which supports young healthcare activists in their quality, safety, and health reform efforts.

3. Describe, in as many details as possible, what the prototype of your product would look like. Then, walk the Challenge reviewers through the typical use of the product, using simple terms and instructions. (1.5 pages)

Our proposed solution, the Behaivior platform, involves generating predictive models that will be trained at the population level and refined at the individual level. We will gather data on all relevant factors that determine relapse risk state - physiology, smartphone usage and location data, self-reports, and support-network-reports. If an intervention is implemented in a timely and customizable manner due to the convenience and accuracy of the Behaivior Predictive Model, the chance of relapse will be reduced.

Here is a hypothetical example, meet Amy. Amy recently finished a 28 day stay in an inpatient treatment facility because that is all her insurance would cover. A few weeks later, her father passes away.

Now Amy's sleep is off, she's smoking more cigarettes than usual, she's skipping her support group meetings, her heart has been racing, she's getting jittery and sweaty. and SHE CAN'T STOP THINKING ABOUT USING AGAIN.

Based on her physiology and behavior, we tell Amy that her patterns resemble a drug craving/obsession state. What does she want to do about it? Amy chooses to see supportive message and photo she set up for herself in advance: It's a photo of her daughter and the message says "I don't want you to screw up your life again, I love you". We then help Amy connect to her 12 step Narcotics Anonymous sponsor, and she is able to make it through this "relapse mode" state without relapsing. The beauty of our technology is that interventions can be completely customized in advance to do whatever people know will help them most in their time of need. Different messages and different interventions work for different people. We are utilizing strategies in behavioral economics and motivational interviewing to nudge people towards positive behavior change. We also plan to detect overdoses and give quicker access to life-saving medications like Narcan. Upon detection of an overdose, EMS would be automatically contacted and GPS coordinates sent. In addition, the phone and/or device would emit an alarm sound to assist medics with finding the individual who overdosed. This is a life-saving device.

Our goal is to be a guardian angel on your wrist-- to help when people might not be motivated enough to help themselves on their own.

On the supervisor side, a treatment facility employee or parole officer has no tools to identify which of the individuals they are responsible are entering a craving state that may lead to a relapse in the near-future. With our solution, a supervisor would have a dashboard to keep track of the population of people in recovery who have opted-in to supervision in order to coordinate interventions.

4. Explain the methods you will use (how, when, where, whom) to determine whether the product is needed by the target audience and whether that audience would be willing to pay for the product. (1 page)

Through two regional National Science Foundation Innovation Corps programs for customer discovery, at Carnegie Mellon University (Spring 2017) and the University of Pittsburgh (Summer 2017), the Behaivior team has conducted dozens of stakeholder interviews to verify the robustness of our proposed solution, confirm our product-market fit, and better understand the needs of the target payers and end-users. Participating in the I-Corps site team programs has set us on a path towards honing in on our business model. We have applied to the national NSF I-Corps program to continue our focus on customer discovery - finding additional potential customers who say "I will use this" and "I will pay for this" through stakeholder interviews. We have a number of new team members who will be assisting us in further customer discovery in 2018, including product managers who have worked for Google and for BodyMedia and Jawbone as well as interns from the Carnegie Mellon University Integrated Innovation program.

When creating our MVP we will employ user-focused design thinking techniques to create a product with optimal user experience. We will combine quantitative and qualitative user research testing methods, including utilization of technologies that track smartphone app usage and ethnographic research methods for user feedback. We will utilize techniques including design sprints, agile development, and rapid iterative testing and evaluation, along with product management tools such as LaunchPad Central, UserVoice and ProdPad.

We have found that addiction relapses are costly for numerous stakeholders who would be willing to pay for a platform that reduced the chance of addiction relapse, and we plan to conduct further stakeholder interviews with these groups to determine which will be initial payers, mid-term payers and long-term payers for a platform that reduces relapses:

- 1. **Families** lose money and peace of mind worrying about the safety of their loved ones who have substance use disorders.
- Inpatient and outpatient treatment programs lose reimbursement money when people leave treatment early, against medical advice, due to relapses.
- Treatment facilities with high relapse rates post-treatment are at a competitive disadvantage.
- 4. Relapses cost **taxpayer and court system dollars** due to higher recidivism and
 additional treatment costs and police costs
 due to drug-related crime.

- 5. For **insurers**, opioid relapses lead to higher treatment costs.
- 6. For **hospitals**, opioid relapses lead to higher emergency room costs.
- 7. **Employers** lose training costs when employees are let go early due to substance use disorders, and employees' productivity is affected when their family members have substance use disorders.

Through extensive research and customer discovery we have identified our primary customer segments. On the end-user side, 25-45 year olds just out of their first stint in rehab will have the greatest likelihood for success with, adherence to, and support of our wearables platform.