Federal Grant Application Project Plan:

Fast Track SBIR Application for Underserved Communities

Presented by Grants Researcher Intern and Policy Analyst,

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Table of Contents

Executive Summary 3

Scope Statement 4

Stakeholder Analysis 8

Work Breakdown Structure 11

Quality Management Plan 13

Budget 14

Risk Management Plan 18

Change Log by Component 19

Lessons Learned 20

Executive Summary

**Why**

Many communities have been particularly neglected by current and ongoing healthcare and policy strategies to combat opioid use disorder (OUD). A combination of inequitable treatment distribution, high treatment costs, and lack of social services makes OUD particularly damaging for nonmajority communities. Behaivior LLC has demonstrated time and again the ability for its *Recovery* system to improve lifelong OUD recovery and reduce OUD treatment costs, meaning Behaivior is poised to provide underserved communities with OUD treatment that will save time, money, and lives. Applying for the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program for the 2021-2022 period will give Behaivior the opportunity to research distribution methods most effective for underserved communities. It will also create the opportunity to research two low-cost alternatives to the current iteration of the *Recovery* system. The first is replacement of the *Empatia E4* with the cheaper *Garmin Vivoactive 4*. The second is the creation of a wearable device-free alternative to the *Recovery* system, a unique trait in OUD treatment services.

**What**

The NIH SBIR program is a federal seed fund for innovative medical projects by small businesses in early development. The research topic relevant to this project is “Innovative Solutions to the Opioid Epidemic for Underserved Communities.” Several phases of the SBIR program are available based on applicant development. Phase 1 projects focus on demonstrating feasibility, technical merit, and commercial viability. Phase 2 projects continue successful research and development efforts. Behaivior will apply to the “Fast Track” phase of the SBIR program. This phase allows applicants to apply for both Phase 1 and Phase 2 simultaneously and be assigned a phase determined most appropriate by the review board. Applying under Fast Track gives Behaivior the most opportunity to demonstrate the value of past research without committing to a particular developmental phase. The project will begin with research on populations underserved throughout the opioid epidemic to demonstrate the value of prioritizing a specific community for this project. Next, the project will identify differences between the current and prior SBIR applications. This will allow Behaivior to reuse prior application materials to save time and keep the application goal-oriented. Additional interns will be recruited into the grant team to reduce the grants team workload. A simultaneous outreach strategy will identify project partners to include in the application document. The project will conclude with the submission of all SBIR materials based on NIH guidelines.

**How**

The project will utilize resources from Behaivior’s prior applications and a considerable number of student interns to minimize the amount of work necessary to complete the application. Interns with grant writing experience will be used to train less experienced interns in grant writing. Clear communication plans and a task spreadsheet shared via Google Docs will minimize confusion among the grants team. The consistent use of the “Comments” feature in Google Docs and regular team updates via a WhatsApp group chat will keep the team updated to any project changes. Finally, assigning no grant writing tasks to the outreach team will give them the time to focus on outreach strategy during the short time frame.

Scope Statement

**Justification:**

While many funding opportunities exist for innovative OUD treatment options, federal grants are particularly important to supporting Behaivior’s growth due to their large financial awards and long project timelines. The National Institute of Drug Abuse (NIDA) has funded a wide variety of commercial products in early stages of development due to the value they could potentially generate for medical science and healthcare. Behaivior will apply for the “Innovative Solutions to the Opioid Epidemic for Underserved Communities” request for applications (RFA) due to its complementarity to Behaivior’s past projects and the feasibility of application completion. Current pilot data has shown that Behaivior’s *Recovery* system has the potential to greatly reduce the likelihood of relapse for persons in recovery (PIRs), greatly improving OUD treatment outcomes and reducing costs. This represents an enormous benefit to all PIRs, but particularly to underserved communities that are consistently priced out of receiving OUD treatment. As such, Behaivior’s *Recovery* system is the ideal project to be supported by NIDA.

The deadline for project completion is 20 August 2021, which is slightly over one month from now. Because federal grant applications are incredibly long and detailed, this is very little time to complete an application. This project will save time while ensuring the application is high quality and complements Behaivior’s current development strategy by reusing materials from a previous SBIR submission. Behaivior’s previous application to NIDA’s Small Business Innovation Research (SBIR) program was for the RFA titled “Innovative Solutions to Substance Misuse among Veterans.” This RFA shares several requirements with the current RFA. First, both target substance use disorders. Second, both require applicants to design their projects around a specific community. Third, the timesaving and lifesaving benefit the *Recovery* system gives to veterans is likely true for other vulnerable populations. Because these projects are so similar, only moderate and RFA-specific edits will be necessary to meet submission requirements.

This project will also save time by utilizing the large number of interns provided by Carnegie Mellon University (CMU) for the summer period. Because many of them likely have limited grant writing experience (particularly federal grants), grant writing workshops will be delivered to ensure they can benefit the project. Note that student interns have a commitment to 300 hours of labor throughout their internship assignment. Because Behaivior recognizes the intern staff is largely unpaid for the internship assignment and also have other educational priorities, the monetary value of intern labor spent on this project will not exceed $2,000. Some transportation costs to attend NIDA informational sessions and meet stakeholders may occur, but these expenses will be kept under $100 due to the narrow timeline of the project.

The use and distribution of a spreadsheet detailing submission requirements is necessary due to the large number of writers contributing simultaneously, most of which being interns with varying levels of experience. By detailing the necessary work via a spreadsheet that is accessible to all team members, the amount of confusion will be greatly reduced. It will also reduce the likelihood of the team failing to include a required component of the application.

This RFA application will be submitted as a Fast Track submission. Because Behaivior has already completed pilot studies which have demonstrated the relapse-reducing effect of the *Recovery* system, the company is more accurately described by the Phase II designation than Phase I. However, both phases would be immensely supportive, with Phase I awards as large as $150,000 and for up to six months and with Phase II awards as large as $3 million for up to two years. Applying under Fast Track gives our application more flexibility by allowing the application to be considered for either phase. While the submission deadline is 31 August 2021, the application should be completed by 20 August 2021 due to the departure of most interns from Behaivior by this date.

This project will explore alternatives to specialization for veteran use for several reasons. First, several substance use disorder (SUD) recovery programs specifically for veterans already service them. As such, communities more underserved than veterans during the opioid epidemic likely exist. Moreover, the RFA is for particularly innovative solutions to OUD and so communities which have fewer services than veterans will yield greater opportunities to demonstrate the innovative potential of Behaivior’s product. Finally, the available data on effective support for veterans suffering from OUD largely suggest providing greater socioeconomic infrastructure like housing assistance and economic support. While Behaivior’s product would greatly benefit veterans by reducing treatment costs, there are not many ways to adapt the *Recovery* system to meet needs unique to veterans. By contrast, adding current plans to research the *Garmin Vivoactive 4* as a wearable device substitute and develop a device-free version of the *Recovery* app would be a quick and effective way to demonstrate specialization for an underserved community. Researching underserved communities other than veterans will provide more opportunities for specializing the *Recovery* system in a meaningful way.

**Description:**

NIDA is the leading agency for scientific research of drug addiction and SUD recovery in the US and is an institute operating under the National Institutes of Health. NIDA announces numerous RFAs every year for a variety of topics under their SBIR program. SBIR awards give small businesses with commercial potential the resources necessary to complete research projects that demonstrate commercial value and establish distribution networks. SBIR awards are given based on one of three main project phases, Phase I, Phase II, and Phase III. Phase I projects are those that aim to demonstrate commercial and scientific feasibility of a potential product and are highly exploratory in nature. Phase II projects build upon prior development and research to demonstrate clinical and commercial viability of a specific product. Phase III projects have already demonstrated the clinical and commercial viability of the product and seek to commercially distribute the product. In addition to having submission options for each project phase, additional submission phases exist for projects which are between certain phases. This project will be submitted as a Fast Track project, which allows projects to be considered for both Phase I and Phase II support.

This project will create an application to an RFA published by NIDA this year titled “Innovative Solutions to the Opioid Epidemic for Underserved Communities.” This RFA aims to fund OUD treatment options that are not currently available in the OUD recovery market. Additionally, the RFA requires that projects target a single community which has been underserved throughout the opioid epidemic and has disproportionately suffered because of it.

The application process will begin by identifying a specific underserved community around which the application will be designed. This will be determined via a research report on the prevalence of OUD among different populations and the OUD treatment services these populations have access to. The findings of this research report will be compiled and used to recommend one underserved community around which the application will be written. Once an underserved community has been chosen, a comprehensive list will be made of Fast Track SBIR application requirements that identifies requirement differences between the previous RFA and the current one. Once key requirements are identified, the spreadsheet of application components used in the previous SBIR submission will be edited to reflect current application requirements and then distributed to the grant writing team. After application component tasks are assigned to team members using the spreadsheet, three or more additional interns will be recruited into the grant writing team to serve as additional writing support for the project.

An NGO and nonprofit outreach strategy will coincide with the underserved community and application task assignment stages of the project. This strategy will allow the outreach team to identify potential project partners relevant to the chosen underserved community. After at least 10 have been identified, they will be invited to an in-person informational session organized by the outreach team to advertise Behaivior’s current project plans and offer partnership opportunities to interested project partners. Once a list of interested project partners has been created, the list will be sent to the grant team to include in the grant application.

Two significant changes will be made to the application to demonstrate specialization for underserved communities. First is the replacement of all references to the *Empatica E4* with *Garmin Vivoactive 4*. These references will be accompanied with descriptions of research plans regarding the *Vivoactive 4’*s medical accuracy and distribution potential. The second change is the addition of a plan to research the clinical benefit of a wearable-device-free version of the *Recovery* system. These plans will be accompanied with explanations of the lack of such monitoring systems in the market and evidence that Behaivior is capable of delivering such a product.

**Deliverables:**

* Research report on underserved communities throughout the opioid epidemic.
* Comprehensive list of SBIR Fast Track application requirements.
* Spreadsheet detailing requirements and status of application components.
* List of project partners to be added to the grant application.
* Completed application document.

**Known Exclusions:**

* Design of new wearable device for underserved groups.
* Discount schemes or new pricing models.
* Research on economic damage caused by the opioid crisis.

**Schedule Objectives:**

* Research report on underserved communities will be completed by 25 July 2021.
* Google Doc outline of application will be distributed to grant team no later than 6 August 2021.
* At least three additional interns will be recruited into the grant writing team by 11 August 2021.
* Application will be completed no later than 20 August 2021.
* Informational session for potential project partners will be held no later than 13 August 2021.

**Financial Objectives:**

* Value of intern labor spent on the project will not exceed $2000.
* Travel expenses for meeting stakeholders and informational meetings will not exceed $100.

**Project Organization:**

Project Sponsor – CEO Ellie Gordon

Project Manager – CFO Arthur Sugden

Grants Department Leader – Aviva Gershovitch

Grant Researcher and Grant Writing Intern – Clayton Caldwell

Secondary Grant Writing Intern – Rachel Mallorie

Data Analysis and Supplementary Grant Writing Intern – Shannon Dutchie

Stakeholder Outreach and Supplementary Grant Writing Intern – Mark Pannon

**Other Information:**

Four grant writing interns are noted under Project Organization. These interns are either assigned to the grant writing team or have already volunteered to participate in the federal grant writing project. The recruitment of at least three additional grant writing interns is done in addition to the four already noted in the team composition.

Stakeholder Analysis

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Primary Stakeholders** | **Role within Project or Company** | **Contribution to Project** | **Project Influence** | **Communication Plan** | **Person Responsible for Communication** |
| CEO Ellie Gordon | Prime Sponsor. | Gives final approval of application and provides suggested edits to written material throughout writing process. | High | Every Monday, Wednesday, and Friday via Zoom following any necessary team meetings or working group sessions (usually 1pm). | Arthur Sugden |
| National Institute of Drug Abuse (NIDA) | Creator of the SBIR program and publisher of the relevant RFA. | Provides all application guidelines and SBIR phase details. Determines award of funds. | High. | NIDA is hosting an informational session on 1 August for relevant RFA details and submission guidelines. The project manager will attend this in person.  NIDA will be provided with a final submission by 31 August. | Arthur Sugden. |
| UPMC Presbyterian | The location of several pilot studies and interviews which serve as evidence for the effectiveness of the Behaivior system. | UPMC is a key project stakeholder due to the testing environment and resources they provide. Including UPMC as a project partner demonstrates Behaivior’s capacity to implement the proposed project. | High. | UPMC’s research department will be contacted by 25 July to organize an in-person meeting with the research planning board to discuss current research plans for the *Vivoactive 4* and *Recovery* system. A follow-up email detailing UPMC’s presence in the application will be sent by 10 August. | Arthur Sugden. |
| **Secondary Stakeholders** |  | | | | |
| Carnegie Mellon University’s Department of Student Affairs. | Provides summer interns from June 1 to August 20. | Receives assessment of intern performance on July 15 and August 15. | Low | A combination of self-evaluations from interns and intern evaluations written by Arthur Sugden will be submitted to CMU’s Student Affairs department by the required dates. | Arthur Sugden. |
| Garmin Ltd. | Producer of the *Garmin Vivoactive 4* wearable medical monitoring device. | Provides endorsement of Behaivior’s testing strategy used in this project. Also provides specifications of *Garmin Vivoactive 4* device used in application. | Low. | Five days after project start (20 June), Garmin will be emailed a request for a presentable list of *Vivoactive 4* specifications to use in the application. Five days before project completion (15 August), Garmin will be emailed the content describing Behaivior’s research plans for the *Vivoactive 4* to ensure Garmin still approves of the research strategy. | Aviva Gershovitch. |
| Previous Partners among PA Rehabilitation Centers | Target market for Behaivior’s OUD treatment tools. | While recruitment of centers to participate in research will likely occur throughout the proposed project, prior centers which participated in Behaivior’s research will be listed as project partners to strengthen the application. | Medium. | The stakeholder outreach team will email previous partners by 5 August for offer to participate in the research elements of the proposed project.  Interested centers will be invited to Zoom informational meeting for project participation on 13 August.  Participating centers will be sent a final email by 15 August detailing their inclusion in the application. | Mark Pannon. |
| Non-grant team interns at Behaivior | Interns work in four main teams across the company throughout the summer period. These teams are Data Analytics, Outreach, Grant Writing, and Coding. | While interns are “assigned” to one role within the company, they have the opportunity to work in different teams when necessary. Additional interns will be recruited from non-grant teams to complete this project. | Medium. | Non-grant teams will be given grants team status updates throughout the project during the Wednesday team meetings on Zoom (5 updates total). Invitation to join the grant team for this project will be extended at this time on 11 August. | Clayton Caldwell |
| Pennsylvania Department of Health (DOH) | The DOH has an active opioid epidemic program and implements several guidelines for healthcare centers and OUD treatment. Successful products by Behaivior require DOH approval for distribution. | The DOH has approved prior pilot programs and will likely approve this project. Prior DOH approval will be included in this project as evidence of Behaivior’s successful research and development. | Low. | Stakeholder outreach department will call the Bureau of Community Program Licensure and Certification (BCPLC) by 9 August to deliver proposed project components and request approval to include the DOH in the application.  BCPLC will be provided a final version of application components relevant to DOH by 25 August. | Mark Pannon. |
| Pilot Study Participants | Persons in recovery who participated in previous studies of the *Recovery* system. | Further demonstrate the demand for Behaivior’s product. Provides data and testimonials from prior clinical trials to be cited as evidence in this application. | Low. | Previous pilot study participants will be contacted via previously-acquired contact info (either phone call or email) no later than 1 August. They will be invited to participate in an early focus group component used in justification of the wearable-free iteration of *Recovery.*  Participants will be contacted between the 20 August project conclusion date and the 31 August submission deadline for additional testimonials they would like included in this application. | Arthur Sugden. |
| Underserved Community NGOs and Nonprofits | Underserved communities are the focus of this application and several NGOs/nonprofits exist which currently serve specific underserved communities. | When a specific underserved community is decided upon, relevant NGOs/nonprofits will be included as project partners to strengthen the application. | Medium. | The stakeholder outreach team should contact relevant stakeholders via email by 5 August with invitations to participate in the underserved community component of the proposed project.  Stakeholder outreach team will organize an in-person informational session for participating stakeholders on 13 August.  Participating stakeholders will be sent a final email by 15 August detailing their inclusion in the application. | Mark Pannon |

Work Breakdown Structure

**Deliverable 1.1: Underserved Communities Research Report Duration (In Days)**

1.1.1 Research which communities are underserved 4

1.1.2 Research which underserved groups have access to specialized resources 4

1.1.3 Consolidate findings into single report 2

1.1.4 Write recommendation for target underserved group. 1

**Deliverable 1.2: Comprehensive Requirements List**

1.2.1 List requirements from “SBIR/STTR INSTRUCTIONS FOR NIH

AND OTHER PHS AGENCIES.” 3

1.2.2 Compare requirements between current and previous RFAs 1

1.2.3 Highlight sections needing redaction from previous RFA 2

**Deliverable 1.3: Application Status Spreadsheet**

1.3.1 List application requirements using previous work plan document 2

1.3.2 Assign spreadsheet tasks to grant writing team members 1

1.3.3 Reassign tasks with new recruits 1

**Deliverable 1.4: Partnership Informational Meeting**

1.4.1 Reach out to potential partners for inclusion 10

1.4.2 Organize project partnership informational meeting 4

1.4.3 Confirm final list of project partners 1

**Deliverable 1.5: Completed Application Document**

1.5.1 Recruit additional interns 3

1.5.2 Create application outline 2

1.5.3 Complete rough draft of application 8

1.5.4 Complete final draft of application 5

Quality Management Plan

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| --- | --- | --- | --- |
| **Measurable Objective** | **Purpose of Measurement** | **Means of Measurement** | **Frequency of Measurement** |
| Less than 10 unaddressed comments on the application draft per week. | Objective gives team members a clear means of collaborating and providing feedback while ensuring that the project is progressing by preventing tasks from piling up. | Grant department leader Aviva Gershovitch will send a count of unaddressed comments in the application draft’s Google Doc to the Whatsapp grants group chat every Thursday evening. | Weekly, starting once application outline has been distributed to the grants team on 6 August. |
| Four progress reports sent to CEO. | Ensures current grant work reflects the CEO’s vision and gives her the opportunity to voice concerns without sacrificing too much of her time. | Typed report of work completed since the previous report and status of current tasks. Sent via email. | On Friday, every two weeks starting 16 July and one sent on 20 August. |
| Two Garmin approvals of *Vivoactive 4* research plan received. | Maintaining approval of Garmin will ensure the application is representative of a major project stakeholder. | Email sent to Garmin to clarify product specs and provide our current plans for using the *Garmin Vivoactive 4.* Approval will be received via email as well. | Twice. First on 20 July and second on 15 August. |
| At least 50 pilot study participants contacted. | Setting a minimum number of pilot study participants increases the likelihood that a viable number of participants can be identified on the application. Doing so would further strengthen the application. | Mark Pannon of the stakeholder outreach department will update the “Partner/Participant Log” and a brief status will be sent to Arthur Sugden via Whatsapp. | Every Sunday until the 1 August due date. |
| At least 10 underserved community NGOs and nonprofits contacted. | Setting a minimum number of feasible community partners increases the likelihood of securing viable project partnerships to include in the application. | Mark Pannon of the stakeholder outreach department will update the “Partner/Participant Log” and a brief status will be sent to Arthur Sugden via Whatsapp. Arthur will also detail partner status for the CEO during the weekly Zoom team meetings. | Mark Pannon’s “Partner/Participant Log” updates will be done every Sunday until the 5 August due date. Arthur Sugden’s status updates in the team meetings will be done weekly until 4 August. |

Budget









|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Probability** | **Description** | **Impact** | **Response** | **Person Responsible** |
| L | Not enough interns volunteer to join the grant team during Deliverable 1.5. | M | Update interns on grant project status throughout the project during weekly team meetings. Repeatedly confirm that interns are allowed to join multiple teams and there are many work opportunities in the grants team. | Clayton Caldwell |
| M | Confusion among team members regarding task assignment and spreadsheet contents, which may lead to project slowdown. | M | Notification of changes to the task spreadsheet will be sent to the grants team via the WhatsApp group chat to ensure all members are aware of work plan adjustments and assigned tasks. | Aviva Gershovitch |
| L | UPMC Presbyterian withdraws support of project. | H | In addition to action noted in the Stakeholder Analysis, expectations regarding the use of UPMC Presbyterian resources conveyed during the 25 July meeting will be conveyed to the grants team to ensure they are represented in the grant application. | Arthur Sugden |
| L | Garmin withdraws support of project. | H | After email of project approval is received from Garmin, *Vivoactive* *4* technical specifications will be distributed to the grant team to ensure the product is described accurately in the grant application. | Arthur Sugden |
| H | No or few stakeholders, community partners, NGOs, and nonprofits attend the informational meeting described in activity 1.4.2. | L | Mark Pannon is given no conflicting responsibilities during the completion of Deliverable 1.4 to ensure sufficient time is spent on outreach. | Mark Pannon |

Risk Management Plan

L = Low

M = Medium

H = High

Change Log by Component

**Budget**

* Split Clayton’s working hours in Deliverable 1 with Shannon in response to an overallocation error in Microsoft Project. Clay is now scheduled to work 141 hours on the project instead of 170.

**Network Diagram**

* Moved Deliverable 1.4 to the first page of the spreadsheet and added the diagram key to the last page. The change makes the diagram more readable and conveys the message that Deliverable 1.4 is concurrent with other deliverable steps instead of occurring at the end of the project.

**Scope Statement**

* Included comments on Deliverable 1.4 and its role in demonstrating project support in Description.
* Added the informational meeting from Deliverable 1.4 to the Schedule Objectives.
* Added Deliverable 1.4 to Deliverables.
* Revised first Financial Objective to reflect maximum limit for labor value of intern work ($2,000).
* Rephrased second Financial Objective for clarity.

**Executive Summary**

* Revised the What and How sections for clarity. Elaborated on the contents of Deliverable 1.4.

Lessons Learned

**Using Microsoft Project to Demonstrate Overallocation**

The use of Microsoft Project was initially time consuming and difficult to handle. However, the software revealed a problem that was initially too abstract to be clearly seen. Despite only being an intern, Clayton dominated the schedule with a total of 170 hours of project work. Because of this, the initial schedule was physically impossible to complete as Clayton would not have had the availability to accomplish all necessary tasks assigned to him without delaying the project. This is partly due to the hypothetical nature of the project design and the bias of describing your own work in a past project, but it is easy for an unequal distribution of labor to occur when project tasks are not described clearly. This is problematic as fluctuations in an uneven work allocation could threaten a project. For example, the project may not have been completed on time with all necessary components if Clayton were suddenly unavailable because more deliverables depended on him than any other team member. Assigning tasks early and checking work using Microsoft Project would have made the grant writing process less dependent on key team members and more resilient to change.

**Clear Codification of Project Goals**

Completing this project plan required considerable work in the early stages to clearly identify project goals. However, generating measurable objectives with a clear date early in the project development process saved time in the long run. For example, scheduling of stakeholder outreach was much easier when considering the timeline for key deliverables. Clearly explaining project goals in writing also kept the project development internally consistent and minimizing necessary revisions. Outlining deliverables while writing the Executive Summary also made describing deliverables in the Scope Statement much easier and ensured those deliverables would be easily re-described in the subsequent Work Breakdown Structure, Network Diagram, and Budget. As a result, the Change Log is quite short.

**Personal Lessons Learned**

Scope clarification is a particularly unpleasant part of project management due to the intense debate among team members and stakeholders which commonly accompany it. However, it is the most important step in implementing a coherent project and ultimately saves time by mitigating revisions. I can remember the many times while interning at Behaivior when I felt I had little or nothing to do. There was certainly work to do, but minimal task assignment and unclear project goals made it difficult for even motivated team members like myself to find work to do. Other interns faced similar challenges. The CEO’s motivation was to give the interns agency in their work. This is noble, but clearly explaining objectives and goals in writing gives those motivated interns something to work with. Additionally, many challenges in a project can emerge from ambiguity, such as creating linchpin network elements (like me) or creating quality control risks. The latter point is particularly relevant as revisions were very frequent throughout the project due an unclear understanding of several application components.