APPLICATION INFORMATION

I. Principal Investigator Information

Title of Project

Title:	Developing a Collaborative Care Model of Office-Based Opioid Treatment for Adolescents

Principal Investigator Information

First name:	Scott
Last name:	Hadland
Degree:	MD, MPH, MS
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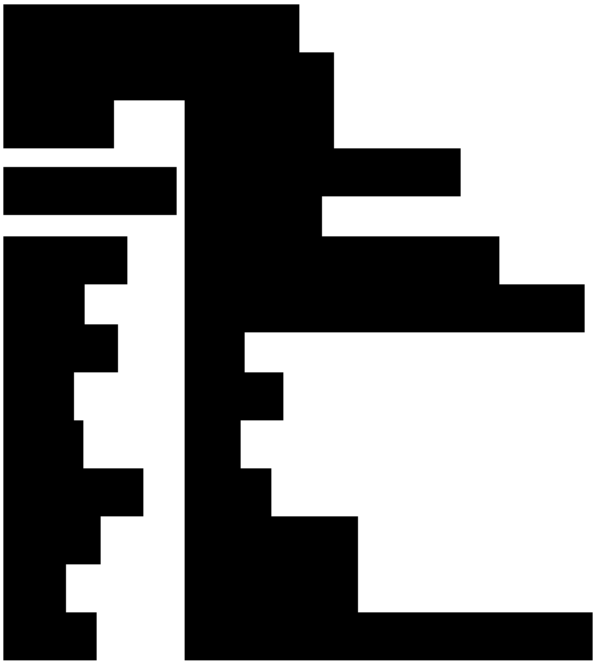
Mentor Information



Department Chair Information

First name:

Last name:

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Department:
Position:
Street
Address
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Zip Code:
Phone:
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Email:

Primary Funding Path:
APA Young Investigator Award

Developing a Collaborative Care Model of Office-Based Opioid Treatment for Adolescents

[redacted]

Academic Pediatric Association Young Investigator (APA YIA)

Primary Mentor: [redacted]

Division Chief: [redacted]

Department Chair: [redacted]

Participation Statement

If funded, I agree to participate in any conference calls and/or in-person grantee meetings (requirements vary by funding track).

[redacted]

SPECIFIC AIMS:

The US opioid epidemic, marked by widespread use of heroin and nonmedical use of prescription opioids, is a public health crisis.[1] Opioid use disorder (OUD)[2] often begins in adolescence.[3,4] Among all people in treatment for OUD, one in three report that their first use occurred before age 18.[5] Providing adolescents with early, effective treatment is critical to improve the life course trajectory of addiction.[6–10] Yet, only one in 12 adolescents who needs OUD treatment receives it, and once in treatment, adolescents are one-third as likely as adults to be retained in treatment.[11]

To promote engagement and retention in care for adults with OUD, office-based opioid treatment (OBOT) is offered in many primary care settings. OBOT combines *(i)* physician visits, including pharmacotherapy when appropriate; *(ii)* nurse care management; and *(iii)* behavioral therapy. OBOT may be especially promising for adolescents, who can receive treatment from a trusted primary care provider in the same familiar setting they receive their usual medical care.[12] To date, however, OBOT has not been formally adapted for adolescents.

This APA Young Investigator Award application proposes to obtain formative quantitative and qualitative data to inform modification of OBOT for adolescents. The Specific Aims are to:

Aim 1: Determine high-risk periods during outpatient OUD treatment for adolescents.

We will quantify retention in care using statewide insurance claims data and identify when risk for loss to follow-up is high, thus informing the timing of support in our OBOT model.

Aim 2: Identify and incorporate necessary modifications to OBOT for adolescents.

We will conduct semi-structured interviews with adolescents and caregivers, focusing on how to best engage and retain adolescents in care, then modify the OBOT clinical model.

These data will allow us to optimize OBOT for adolescents and will provide preliminary data for a K23 career development award application in which I will propose a pilot trial of the model.

BACKGROUND:

The US opioid crisis has been declared a public health emergency.[1] From 2014 to 2015, overdose mortality for 15- to 19-year-olds rose 19%, more than doubling the 1999 rate.[13] Engaging adolescents in early treatment is critical to prevent lifetime harm.[6 10] Yet, only one in 12 adolescents who need treatment receive it,[14] and once in treatment, adolescents demonstrate poor retention in care.[11 15 16] For adults with OUD, many primary care clinics offer Office-Based Opioid Treatment (OBOT), an evidence-based, collaborative care approach that optimizes engagement and retention in care by combining *(i)* physician visits, *(ii)* nurse care management, and *(iii)* on-site behavioral therapy.[17 19] OBOT is especially promising for adolescents, who can receive treatment from a trusted primary care provider in the same familiar setting they receive their usual medical care.[12 20]

Adolescents have unique physiological, neurocognitive, and psychosocial needs distinct from those of adults,[21] and to be effective, drug treatment for adolescents should be developmentally appropriate.[12 20 22 25] Specifically, the developmental stage of adolescents should be considered with regard to goals for treatment, intervention components, timing of components, and integration with other support systems (*e.g.,* schools, workplaces, community groups). Additionally, many adolescents present to addiction care with a parent, guardian, or other trusted adult, and incorporating caregivers into treatment in many cases may improve treatment outcomes.[8 20 25 28] *In order to address these requirements of an effective treatment model for adolescents – that services be developmentally appropriate and family-centered to maximize engagement and retention – OBOT needs modification and rigorous study.*

SIGNIFICANCE:

The clear and urgent need for improved treatment services for adolescents (defined here as young people <18 years) was highlighted by a 2016 American Academy of Pediatrics policy statement – the first of its kind by any pediatric professional society.[20] The statement calls for

expanded addiction treatment in *primary care*, an approach that has been shown to be effective for adults with OUD.[17 18] In order to overcome common barriers to providing OUD treatment in primary care (including insufficient provider support and infrastructure),[29 32] the Substance Use and Mental Health Services Administration has promoted OBOT to enhance engagement and retention in care.[17 18 33] *However, OBOT has not yet been studied for adolescents, thus constituting a critical knowledge gap amidst calls for expanded treatment for this age group.*[20 34]

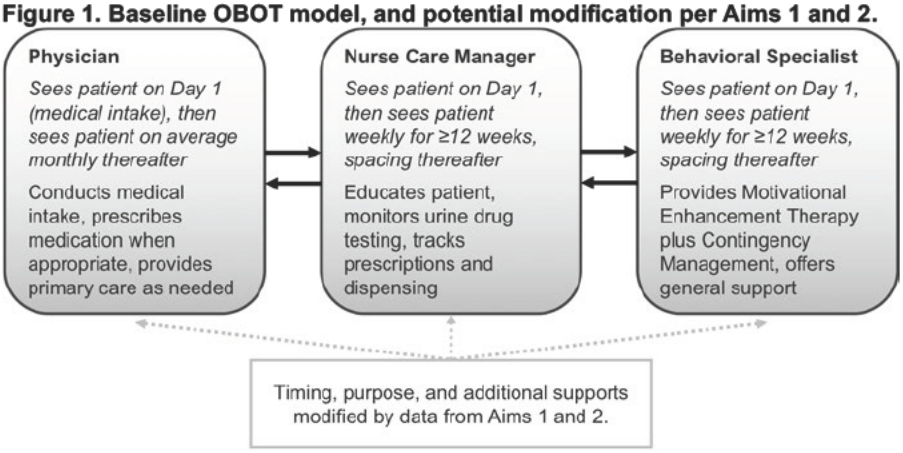
An OBOT model enhanced for adolescents has enormous potential to improve treatment outcomes. Yet, even when effective for the treatment of adults, behavioral health care models for adolescents are often hampered by poor engagement and retention in care.[35] OBOT is evidence-based for treating adults with OUD,[17 19 33] but the treatment model does not fully address the unique needs of adolescents. In one study of OBOT, young people were only one-third as likely to be retained in an adult-oriented program despite a collaborative care approach.[11] Relapse during and after treatment among adolescents is common.[11 36 37] An OBOT model optimized to meet the needs of adolescents holds great promise to maximize engagement and retention.[38 40] In turn, engaging and retaining adolescents in the evidence-based OBOT model is likely to maximize treatment outcomes. *Adapting OBOT for adolescents is innovative, holds great promise to improve outcomes, and is consistent with the Academic Pediatric Association's mission of optimizing health and well-being for vulnerable young people.*

PRELMINARY STUDIES:

In June 2016, BMC established one of the first OBOT programs for adolescents. Clinic staff includes three physicians, a nurse care manager, and a behavioral specialist. **Figure 1** depicts the current OBOT program (based on the adult-oriented model[17 18]) and the role and timing of visits with each care team member. Although the model still requires optimization for adolescents, the program has already cared for 104 patients. Overall, 57% are male; and 58%

are non-Hispanic white, 13% are non-Hispanic black, and 29% are Hispanic.

Figure 1. Baseline OBOT model, and potential modification per Aims 1 and 2.



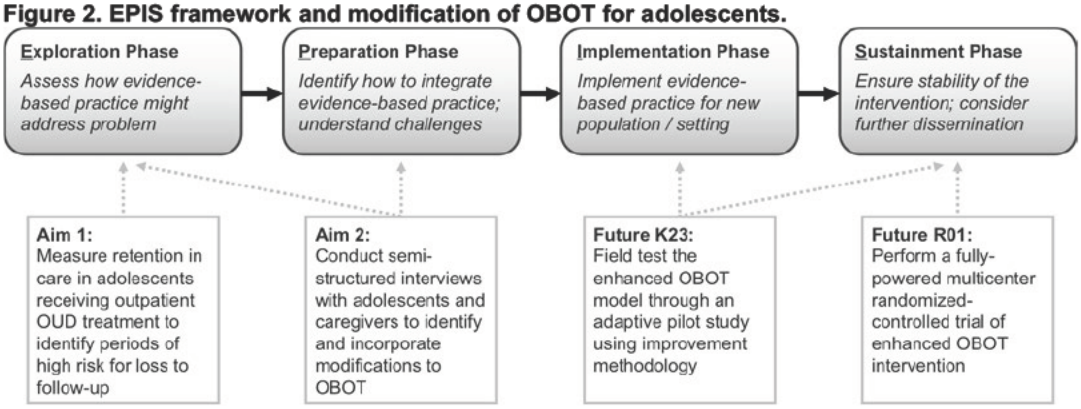
To begin to understand what modifications will be needed for our OBOT program, from July to September 2017, I conducted semi-structured interviews with 15 key informants from across the US, including providers who treat adults with OUD (physicians, nurse care managers, behavioral health specialists) and pediatric providers working in areas of high OUD prevalence who do not yet provide OUD treatment. Key informants recommended that our enhanced OBOT model: *(1)* consider a broad range of treatment outcomes (in addition to abstinence/reduction in use, also measure reengaging with family, participation in school/work, engaging in prosocial sober activities), *(2)* maximize accessibility (provide afternoon/evening and drop-in hours, assist with transportation through bus passes and parking), *(3)* offer developmentally appropriate care (ensure confidentiality is explained/addressed, consider near-peer or group support, offer education on addiction and the developing brain), and *(4)* involve family in recovery (spend time with adolescents and caregivers together/separately at every clinical visit, incorporate caregivers into treatment plan). Input from patients and caregivers is now needed to further inform our model development.

DETAILED METHODS & ANALYSIS PLAN:

In order to develop, modify, pilot, and optimize the enhanced Youth OBOT model, I will adhere to the systematic *Exploration-Preparation-Implementation-Sustainment (EPIS)* framework,[41 42] a model for implementing evidence-based clinical interventions in new settings for new

populations (**Figure 2**). Aim 1, in which I quantify retention in OUD

Figure 2. EPIS framework and modification of OBOT for adolescents.



treatment, informs the *Exploration Phase* of EPIS. Aim 2, in which I conduct semi-structured interviews with youth and caregivers, further informs the Exploration Phase, and drives the *Preparation Phase*, in which I identify and integrate necessary modifications into the model. A future pilot trial (funded by a future proposed K23 career development award) will underlie the *Implementation Phase* and inform ways to sustain the model, critical to the *Sustainment Phase*.

Aim 1: Determine high-risk periods during outpatient OUD treatment for adolescents.

Objective. To identify periods of time for high risk of loss to follow-up among adolescents <18 years receiving outpatient OUD care in [redacted] and to identify subgroups of youth at elevated risk for loss to follow-up in order to inform timing of more intense support during OBOT.

Hypotheses. I hypothesize that <25% of youth will be retained in care at 6 months, with highest risk for loss to follow-up occurring during the first month, and risk decreasing with each subsequent month in treatment.[11 15 16]

Rationale. Using Department of Public Health data that exhaustively capture all private and public health insurance claims within [redacted],[43] we will identify all adolescents <18 years receiving medications for addiction treatment (buprenorphine or naltrexone) in outpatient settings. This sample is a close approximation of the clinical population of youth with OUD in treatment at [redacted]. By identifying when during treatment youth are at risk for loss to follow-up, analyses will inform the timing and purpose of OBOT intervention components (Exploration

Phase of the EPIS framework).[41] For example, if risk for loss to follow-up is high during the first month of treatment, we will consider increasing the frequency of clinical visits and behavioral support during this time, and we may further increase support for high-risk youth subgroups.

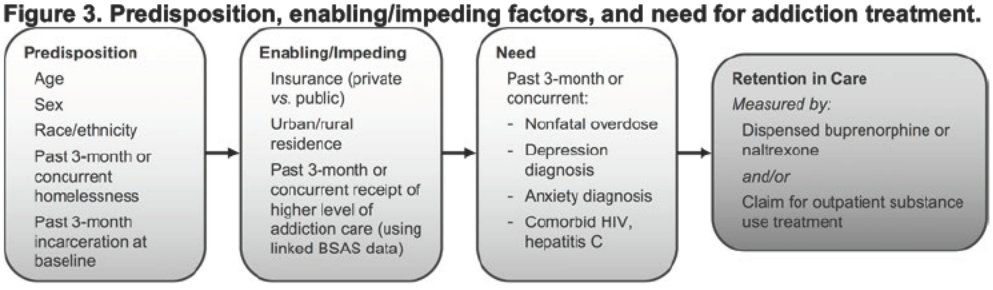
Theory. Our approach is guided by the Behavioral Model for Vulnerable Populations (**Figure 3)**,[44] which has been used to guide research on addiction treatment utilization, including among youth.[45 47] The model posits that retention in care is a function of *(i)* an individual's predisposition to use health services; *(ii)* facilitators and barriers to use, called enabling and impeding factors, respectively; and *(iii)* an individual's need for care.[44] The model has guided our selection of predictor variables (all shown in **Figure 3** are available in the MDPH data).

Design. Retrospective cohort study of adolescents with OUD in [redacted], 2011-2015.

Data source. Through 2015 legislation under Chapter 55,[43] the novel [redacted] Department of Public Health (MDPH) dataset links individual-level information from *(1)* the All Payer Claims Database[48] with data on all public and private insurance claims for inpatient, outpatient, and emergency department visits; *(2)* medication dispensing at pharmacies; and *(3)* treatment data from the Bureau of Substance Abuse Services, with information from all state inpatient, residential, outpatient, and detoxification programs. *This novel dataset adheres to all MDPH dataset generation quality standards,[49] and though new, has already been successfully used by [redacted] investigators (including collaboration with the Principal Investigator, Dr. [redacted]) to study retention in care among older adults and to validate all variables shown in* ***Figure 3***.[50 52]

Sample. Inclusion criteria will be age <18 years, diagnosis of OUD, and receipt of buprenorphine or naltrexone in an outpatient treatment setting. Consistent with prior studies, youth will be defined as receiving a diagnosis of OUD if a claim was

Figure 3. Predisposition, enabling/impeding factors, and need for addiction treatment.



filed with a primary or secondary ICD-9-CM diagnosis code for OUD (304.0x or 304.7x) in ≥1 inpatient or emergency department claim or ≥2 outpatient claims.[53 54] Prior to the first observed diagnosis of OUD, a preceding period of 60 days will be required without a claim containing an OUD diagnosis or buprenorphine or naltrexone dispensing to define a new episode of care.[53 55] Youth receiving methadone will be excluded since methadone is necessarily dispensed only in methadone treatment centers rather than in outpatient settings.[20 56] *Within the MDPH dataset, I have already identified a cohort of* n=*979 individuals that meet inclusion criteria*.

Outcomes. The primary outcome will be retention in care, defined as time from initiation of buprenorphine or naltrexone in an outpatient setting until loss to follow-up (≥60 days without a claim[55]). The last day of retention in care will be the date that an individual was dispensed medication *or* the last date of an outpatient claim (*i.e.,* if a participant discontinues medication but remains in outpatient addiction care), whichever is later.[55 57 60]

Analyses. I will first describe baseline cohort characteristics and use the Kaplan-Meier technique to generate survival curves of retention in care. I will then conduct Cox proportional hazards regression comparing time to loss of follow-up. Multivariable models will identify the contribution of the predisposing, enabling/impeding, and need factors shown in **Figure 3**. Additionally, we will incorporate data from the Bureau of Substance Abuse Services on whether an individual received *(i)* acute treatment services ("detox"), *(ii)* crisis stabilization services or transitional support services, or *(iii)* long-term residential addiction treatment. We will generate time-varying indicator variables for each level of treatment, and examine retention in care in relation to receipt of these services in multivariable models.

Limitations. The analysis of retention in care and relapse among youth is limited to those who receive buprenorphine or naltrexone; the MDPH data are unable to conclusively identify youth receiving outpatient addiction treatment that does not incorporate pharmacotherapy. However, since most youth (86%) in the [redacted] OBOT program ultimately choose to receive buprenorphine or naltrexone, youth in the MDPH receiving pharmacotherapy in outpatient settings are a close

approximation of youth in the [redacted] OBOT program.

Aim 2: Identify and incorporate necessary modifications to OBOT for adolescents.

Overview. To further inform modification of the OBOT model (Exploration Phase of the EPIS framework),[41] I will conduct qualitative research to identify modifications that will maximize engagement and retention in care, and render the model developmentally appropriate and family-centered. This work will be comprised of semi-structured interviews with adolescents and caregivers. Then, to incorporate identified modifications into OBOT (Preparation Phase),[41] I will use the systematic approach of Wingood and DiClemente,[61] as described below.

Inclusion criteria. *Adolescents:* Age <18 years and diagnosis of OUD, based on a physician intake interview using DSM-5 criteria.[2] *Caregivers:* Parent/guardian of a <18-year-old with OUD. Although we will aim to enroll adolescent-caregiver dyads, adolescents may enroll if their caregiver does not participate, and vice versa.

Sampling and recruitment. A trained research assistant (RA) will conduct targeted outreach to patients and caregivers of the [redacted] adolescent OBOT program. I will use purposive sampling to maximize diversity of the sample with regard to age, sex, race/ethnicity, and prior treatment experiences.[62] The RA will approach potential participants, explain the study, and obtain informed consent. A Certificate of Confidentiality (now routinely provided by NIH) will protect participants given the potential that they may disclose sensitive information. Recruitment will continue until thematic saturation has occurred, and I estimate requiring 12-15 adolescents and 12-15 caregivers. Adolescents and caregivers will each receive a $30 gift card as remuneration.

Semi-structured interviews. I will personally conduct in-person semi-structured interviews, and will use separate interview guides for adolescents and caregivers. Interview guides will be developmentally appropriate and I will field test them prior to use. Interviews will proceed from broad, introductory questions to more specific probes.[63 64] Probes will examine the feasibility and acceptability of addiction treatment in primary care, facilitators/barriers to engagement and

retention in care, and specific recommendations that would optimize OBOT for adolescents.

Qualitative data analyses. I will use an inductive approach to identify themes and subthemes.[65] First, the RA and I will independently read a subset of transcripts to generate potential codes, with oversight by my mentors/advisors.[66] We will use these data to develop a preliminary codebook, which we will then apply to a different set of transcripts to assess consistency across themes and revise as needed. We will then apply the final coding scheme to transcripts using NVivo software. We will analyze content for emergent themes/subthemes, and consider the context of sociodemographic factors (age, sex, race/ethnicity) and participants' prior experiences with other treatment models to delineate OBOT modifications.[65]

Integrating modifications to OBOT model. My mentors and I will use findings from this formative research (Aims 1 and 2) to design the enhanced OBOT model using the systematic approach of Wingood and DiClemente.[61 67 68]. First, we will decide on modifications to be incorporated, bearing in mind real-world financial, time, and regulatory constraints. Second, we will develop a draft plan for the clinical model, balancing modifications with the need to maximize fidelity and sustainability. Third, we will invite key informants (*i.e.,* participants of our prior qualitative research) to assess the credibility of our draft plan and refine as needed through a process known as member checking,[69] thus developing a final plan for the pilot.[64 65] Fourth, we will train [redacted] clinic staff on the enhanced OBOT program in preparation for its implementation.

CAREER DEVELOPMENT:

The career development goals supported by this APA Young Investigator Award are to: (1) establish expertise in analytic techniques used in interventional research, including advanced survival analysis and use of correlated data; and (2) develop foundational skills in intervention development, including the use of qualitative data to inform an intervention. To support Goal 1, I will build on my preexisting experience conducting basic time-to-event analyses and will seek additional formal education by attending the 3-day UCLA *Center for Advancing Longitudinal*

Drug Abuse Research (CALDAR) Institute, which provides advanced training in survival analysis in relation to substance use research. To support Goal 2, I have already established early skills in qualitative data analysis and intervention development by attending programming through the [redacted] Center for Implementation and Improvement Sciences at [redacted] University, and will continue to attend this ongoing seminar series with my primary mentor, Dr. [redacted].

KEY PERSONNEL:

[redacted]**, MD, MPH, MS**, the Principal Investigator, is an early career clinician-investigator with triple board certification in General Pediatrics, Adolescent Medicine, and Addiction Medicine, and prior research experience in clinical epidemiology. He is an Assistant Professor of Pediatrics at [redacted]. He will direct all aspects of the study, including overseeing data collection, analysis, preparation of reports and manuscripts, and completion of required reports to the APA. [redacted]**, MD, MPH**, the Primary Mentor, is Professor of Pediatrics, [redacted]. Dr. [redacted] is a national expert in developing and implementing behavioral health interventions in pediatric primary care and is an R01-funded investigator. Dr. [redacted] office is located across the hall from Dr. [redacted], and will meet in person with him weekly. [redacted]**, MD, MPH, MA**, a Co-Mentor on this application, is [redacted] of General Internal Medicine and [redacted] the Department of Medicine at [redacted]. Dr. [redacted], an internist, is an internationally recognized expert in addiction research with a long history of R01 and U-level funding. Under Dr. [redacted] oversight, the Section of General Internal Medicine developed, implemented, and disseminated one of the first national models of OBOT. He will meet with Dr. [redacted] biweekly.

Timeline	Months			
1. Secondary data analysis.	**1-3**	**4-6**	**7-9**	**10-12**
Conduct analyses	•	•		
Prepare manuscript(s)		•	•	
2. Qualitative research.				
Train RA	•			
Recruit / interview adolescents	•	•		
Recruit / interview caregivers	•	•		
Analyze data modify OBOT		•	•	•
Prepare manuscript(s)			•	•

BIOGRAPHICAL SKETCH

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NAME: [redacted]

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: Assistant Professor of Pediatrics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
[redacted]			

A. Personal Statement

As a general pediatrician with subspecialty certification in adolescent medicine and addiction medicine, I bring firsthand clinical knowledge to my research. Since 2007, I have conducted epidemiologic studies examining substance use and mental health outcomes among at-risk adolescents. In my other research endeavors, I have identified associations between state-level alcohol policies and adverse health outcomes such as adolescent drinking, alcoholic cirrhosis, and motor vehicle accidents; critically reviewed the literature on the long-term consequences of regular marijuana use among adolescents; and conducted systematic and narrative reviews of medical home-based interventions for adolescents.

In the face of a worsening opioid and overdose epidemic, my work aims to identify treatment gaps for adolescents with opioid use disorder and develop interventions for the medical home to address these gaps. In this Academic Pediatric Association Young Investigator Award application, I propose acquiring additional training in advanced survival analysis and qualitative research, and pursuing a research plan to understand how best to reshape clinical interventions for adolescents with opioid use disorder. Using the knowledge acquired from projects proposed in this application, I will then develop a plan to adapt office-based opioid treatment (OBOT) for adolescents under the guidance of mentors with substantial expertise.

1. [redacted]

B. Positions and Honors

Positions and Employment

[redacted]

Other Experience and Professional Memberships

[redacted]

Honors

[redacted]

C. Contribution to Science

1. Since 2007, I have conducted epidemiological research with the [redacted] under the mentorship of [redacted], MD, PhD. A focus of our work has been substance

use among street-involved adolescents and young adults enrolled in the [redacted] Study [redacted], an NIH-funded prospective cohort study. Through our collaboration I have written 13 first-author, peer-reviewed publications highlighting associations between substance use, drug injection, access to treatment, and infectious diseases such as HIV and hepatitis C virus.

a. [redacted]

2. My research with the [redacted] Study [redacted] has also focused on mental health, access to treatment, and adverse childhood experiences. Mentored by [redacted], MD, PhD, I have studied the adverse health and psychosocial consequences of injection drug use, particularly of prescription opioids of heroin. This work has demonstrated the excess risk for injection-related harm in this vulnerable population, and highlighted gaps in treatment availability, accessibility, and acceptability for homeless youth.

[redacted]

3. Through a collaboration with the Center for [redacted] Research at [redacted] Children's Hospital, I conducted narrative reviews of the potential adverse health, neurocognitive, and psychiatric consequences of regular marijuana use among adolescents and young adults. This work has served to inform pediatric clinical practice and has been highly cited in the lay media.

[redacted]

4. Under the mentorship of [redacted], MD, MPH, I conducted analyses linking state alcohol policies to youth drinking and alcohol-related mortality. Our most recent analysis examines policies in relation to motor vehicle injury fatalities among underage youth. An abstract based on this work resulted in my receipt of the Society for Adolescent Health and Medicine (SAHM) New Investigator Award in [redacted]. Whereas previous studies have examined the effect of single alcohol policies, our work has demonstrated the potential protective effect of states' overall alcohol policy environments (*i.e.,* collection of policies) in preventing early mortality.

[redacted]

[redacted]

5. With [redacted], MD, MPH, I conducted a systematic review of the medical home for healthy children. Using PRISMA methodology, we examined studies linking pediatric care in a medical home to beneficial outcomes, such as receipt of vaccines, recommended screening, and anticipatory guidance. This analysis of the medical home serves as a basis for how I might develop primary care-based interventions for substance use in my future research, and other manuscripts listed below are review articles that address primary care-based management of substance use disorder.

[redacted]

Complete List of Published Work:

[redacted]

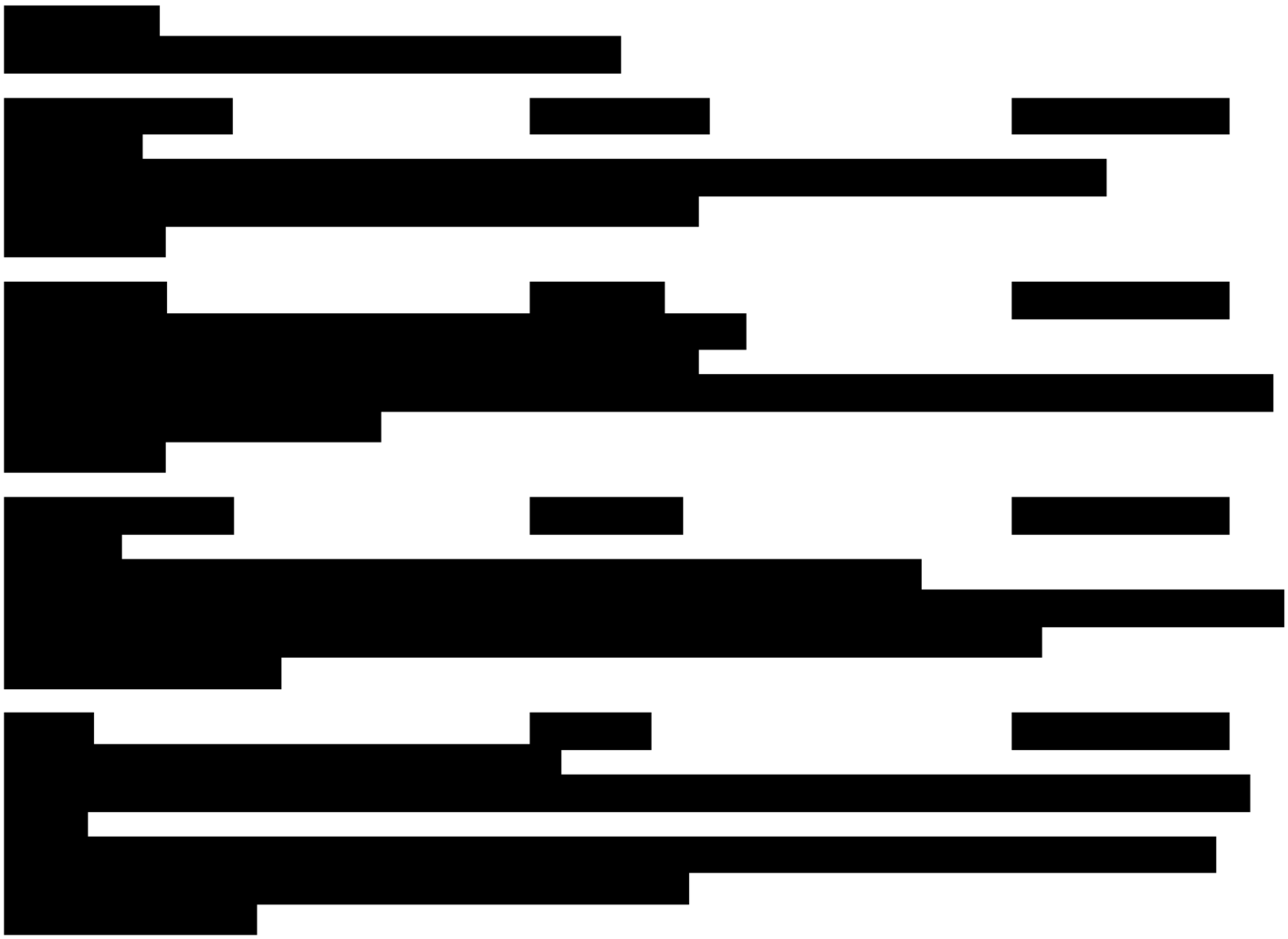
D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

[redacted]

Completed Research Support

[redacted]



BIOGRAPHICAL SKETCH

Prov de the fo ow ng nformat on for the Sen or/key personne and other s gn f cant contr butors.
Fo ow th s format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: [redacted]

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: Professor and Vice Chair [redacted]

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
[redacted]	[redacted]	[redacted]	[redacted]

A. Personal Statement

As a Professor of Pediatrics at [redacted], and the Associate Chief Medical Officer for [redacted], I have had the opportunity to mentor over 20 junior faculty, fellows, residents, and students. I have spent over 10 years leading clinic-based behavioral health trials; and recently, under the auspices of a K24 award ([redacted]), I have expanded my research to include implementation studies. I am strongly committed to mentoring Dr. [redacted] in his Academic Pediatric Association Young Investigator Award application as he seeks to transition from epidemiologic to interventional research. Drawing on the expertise of his interdisciplinary mentorship and advisory team, I will guide and support Dr. [redacted] as he takes formative steps to adapt a primary care-based addiction treatment model (office-based opioid treatment) in his proposed research. My prior experience in developing and delivering behavioral health interventions in primary care will be central to my role as Dr. [redacted]'s mentor. My expertise will be complemented by that of another mentor, Dr. [redacted] MD, MA, MPH, an international leader in primary care-based interventions to address opioid use disorder among adults; I will serve a central role in helping Dr. [redacted] understand how to adapt treatment models developed by Dr. [redacted] to render them developmentally appropriate and family-centered for adolescents.

B. Positions and Honors

Positions and Employment

[redacted]

[redacted]

C. Contribution to Science (publications drawn from a total of 55)

1. **Interventions and services to promote healthy development among low-income children.** My interest in interventional research focusing on child development began during my fellowship in the Robert Wood Johnson Clinical Scholars Program. My first project in this area was an evaluation of an early literacy program to promote kindergarten readiness; my second, a multisite randomized trial of an approach to enrolling low-income children in high quality preschool. Most recently, we published a comparative effectiveness trial, examining the differential impact of two collaborative care systems for urban children with ADHD. The unifying theme of this body of work is engaging health systems – in both medical and community-based settings.

[redacted]

2. **Relationship between maternal depression and child health.** Because of my interests in child development and school achievement, I focused much of my early career research on the impact of maternal depression on children. This work help to build the case that preventing depression among urban mothers could plausibly provide long term benefit to two generations. This work was funded through a Robert Wood Johnson Physician Faculty Scholars award. This observational research has informed subsequent intervention development and testing.

[redacted]

3. **Development and testing of interventions to prevent depression among low-income mothers.** Beginning with an NIMH K23 award, I began to lay the groundwork for a lay-delivered intervention to prevent depression among low-income mothers. The intervention, now manualized and copyrighted in its

basic format, is based on the cognitive-behavioral principles of Problem Solving, and has been designed as a scalable, low-cost intervention model with public health applicability. We currently have two R01-funded trials in the field – one, in Head Start preschool programs; the other, in four neonatal intensive care units (NICUs). Both trials measure depression symptom trajectories in the mothers. The Head Start trial also measures indices of kindergarten readiness among the preschool-aged children; and the NICU trial measures socio-emotional development among the infants.

[redacted]

4. **The role of violence and trauma in moderating maternal depression's impact on children.** Our research group has consistently identified violence and trauma as important moderators of maternal depression's impact on children, as well as critical moderators of the impact of our intervention strategies. This consistent finding, cited in 2009 by the Institute of Medicine, has important public health implications regarding the differential efficacy of depression treatment and prevention models for different populations.

[redacted]

5. **Mentoring.** My final area of scientific contribution is mentoring. Over my time at [redacted], I have mentored over 20 junior faculty members, fellows, and residents. These mentoring activities – now codified in a recently funded K24 award from NICHD – occupy about half of my total effort.

[redacted]

Complete List of Published Work in MyBibliography:

[redacted]

Research Support

Ongoing Research Support

[redacted]

Completed Research Support (within the last three years)

[redacted]

[redacted]

[redacted]

December 15, 2017

Members of the Review Committee:

I am honored to serve as Dr. [redacted] primary mentor for his application for an Academic Pediatric Association (APA) Young Investigator Award (YIA). I have known [redacted] for approximately eight years – beginning when he was an intern in our pediatric residency program, and intensifying over the past two academic years when we successfully recruited him to the [redacted] faculty. [redacted]'s APA YIA study plan is an outstanding fit for his research talents and his passion for working with adolescents and young adults with opioid use disorder (OUD) and their families. [redacted] proposes two linked studies that will provide important data needed to create sustainable and scalable interventions to help youth with OUD and their families access timely, effective services.

Although [redacted]'s research has long been active in the area of youth substance use, his emphasis has changed recently to focus on interventional research. During his fellowship training in adolescent medicine and health services research, he completed several epidemiologic studies of youth substance use, including multiple first-author publications in *Pediatrics* and *JAMA Pediatrics*, and was the recipient of the *JAMA Pediatrics* Trainee Award and the Society for Adolescent Health and Medicine's New Investigator Award. He also published a first-author commentary on managing OUD in primary care for *The Lancet*. Over time, [redacted] has been increasingly committed to pivoting from completing epidemiologic studies to designing and implementing interventions that can impact addiction early in the life course. For this reason, I will serve as his primary mentor as he focuses on the formative quantitative and qualitative research he has proposed in his APA YIA application to develop a thoroughly informed intervention for adolescents with opioid use disorder.

I believe I am well qualified to mentor [redacted] and will provide him with mentorship as he modifies and optimizes Office-Based Opioid Treatment (OBOT) for youth. In much the same way that [redacted] has proceeded in his career, I developed a series of interventions to improve behavioral health outcomes in the context of primary care, particularly for a low-income, minority population with the goal of improving health equity and reducing disparities. Currently, I am conducting a series of NICHD and NIMH-funded studies directly relevant to this work [redacted], and am currently a mentor for four K awardees conducting interventional research. I have also mentored three mid-career faculty members in our Department to help them garner R01 or major foundation support, following completion of their career development awards.

I will ensure that he has the faculty resources needed to pursue additional training. For example, [redacted] plans to attend the University of California Los Angeles *Center for Advancing Longitudinal Drug Abuse Research (CALDAR)* Summer Institute in order to advance his analytic skills in substance use research, and our Division will ensure his travel expenses are covered. (He is requesting funding from the APA YIA to purchase course materials only.) Directly pertinent to [redacted]'s APA YIA proposal, I have been awarded an NIH K24 award [redacted] that focuses on implementation and improvement science. This K24 guarantees that I will have the time to devote to Scott's career development. I am also PI of a Primary Care Training

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Enhancement award from HRSA to train junior faculty members in real-world systems change, and this award specifically outlays funds to enhance our understanding of how best to treat opioid addiction in the field of pediatrics. Lastly, I have real world experiences that will help [redacted] contextualize his work within existing systems of clinical care: I currently serve as a member of the United States Preventive Services Task Force, which makes evidence-based recommendations about clinical preventive services for primary care, and was recently appointed as Associate Chief Medical Officer for Population Health at [redacted].

To ensure that [redacted] meets his educational and research objectives, I will meet with him one-on-one on a weekly basis, and participate in joint meetings with his other mentors and advisors quarterly to oversee his progress. His Co-Mentor, Dr. [redacted], MD, MA, MPH, is a NIDA- and NIAAA-funded researcher who oversaw the development, implementation, and dissemination of OBOT at [redacted] and throughout the United States. [redacted] and I already meet weekly to discuss his current work. These meetings will continue with [redacted]s APA YIA award. I expect that we will also have multiple informal meetings each week, as his office is directly across the hall from mine – and we both work with our doors open.

[redacted]'s goal to improve the health of vulnerable youth through promoting the adoption and spread of effective primary care-based interventions aligns perfectly with the research being conducted by other members of our Division. The Division of General Pediatrics will provide financial and human resources above that provided by the APA YIA to allow him to accomplish his study plan. [redacted] will be able to hire research assistant(s) from the pool of research assistants already working in our Division. Many of these individuals have specific experience assisting with studies similar to those proposed in [redacted]'s application, including in the area of behavioral health. [redacted] will also have access to data analysts from the research group that I manage. Should [redacted] require more research assistant time than is available in his budget, my team will provide that for him with institutional funds. As Chief of the Division of General Pediatrics, I also guarantee that he can conduct his work within the pediatric primary care center at [redacted].

[redacted]'s project is of extreme importance. Opioids have exacted an enormous toll on the people of Massachusetts and the United States, and very few clinicians or researchers have turned their focus to upstream interventions that address addiction among young people. This APA YIA application represents a first step in a research trajectory to change this and to optimize the long-term health and development of this vulnerable population.

Sincerely,

[redacted]

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BUDGET JUSTIFICATION

Item	Detail	In-kind (optional)*	Amount requested from APA	Total Amount	Justification
Research Assistant	$25/hr of RA time x 200 hrs	$1,095*	$3,905	$5,000	A research assistant will support Dr. [redacted] in all aspects of the proposed research, including the day-to-day administrative operations, obtaining IRB approval, recruiting and enrolling participants, obtaining transcripts for qualitative interviews, and disbursing compensation to participants who complete study activities.
Transcription	$96/hr of audio x 1 hr/subject x 30 subjects	$0	$2,880	$2,880	A transcription service (Private Secretary, Inc.) will be employed to transcribe audio files of the semi-structured interviews with adolescents and caregivers into text.
Remuneration	$30/subject x 30 subjects	$0	$900	$900	Each adolescent and caretaker will receive a $30 ClinCard (a secure reloadable debit card developed by Greenphire, Inc.) for their time participating in the semi-structures interviews.
Software, type	*Stata* 15/SE single academic license *NVivo* single academic license	$0 $545*	$365 $0	$365 $545	*Stata* statistical software will be used for quantitative analyses. *NVivo* qualitative software will be used to analyze data and apply the final coding scheme to transcripts.

PAS Travel	(max $1500)	$500*	$1,500	$2,000	Dr. [redacted] will travel to PAS to present his findings, disseminate his research, learn about innovations in his field, and network.
Research training	CALDAR 2018 Summer Institute, Los Angeles, CA, August 2018	$1,500*	$450	$1,950	$450 is requested to support registration and materials for the *UCLA Center for Advancing Longitudinal Drug Abuse Research*, a course designed for young investigators to learn longitudinal data analysis techniques applied to substance use research; travel costs ($1,500) will be covered in-kind.
TOTAL		**$3,640***	**$10,000**	**$13,640**	

*In-kind funds will come from the Division of General Pediatrics at [redacted].