

# Independent Investigative Inquiry (III) Scholarship of Discovery Project Proposal Form



Students who choose Scholarship of Discovery can expect to learn and develop the skills of designing a research question, and the methods involved in answering that question through data collection and analysis.

Your Project Proposal should be brief; in addition to the Cover Sheet, Project Timeline, Human and Animal Subjects Form, and Faculty Mentor Statement, it should be 3-4 pages, double spaced, 12-point font, and clearly describe what you plan to do. You are welcome to use images or graphs to help convey your plan. Key items to include in your Project Proposal are:

1. Background & Hypothesis
2. Study Design & Methods, to include:
  - a. *Population (inclusion/exclusion criteria; recruitment procedures)*
  - b. *Sample Size (ideal vs. achievable)*
  - c. *Variables and how they will be measured (outcomes; exposures; potential confounders)*
  - d. *Procedures for data acquisition (attach data sheets, questionnaires, etc.)*
  - e. *Methods for data analysis*
3. Expected Significance of Results
4. Clearly define your role in the project
5. Preliminary Literature Search (5-10 references that address your research question)

You will work with a **Faculty Mentor** who may be any UWSOM faculty member with an Affiliate, Clinical, or Regular faculty appointment, including those at the Instructor level. Fellows and residents are **not** eligible to be a mentor or co-mentor. Your Faculty Mentor must be experienced with the topic and methods used in the study. Their role is to help you plan your study, meet with you regularly (weekly at minimum) during the execution of the project, review your poster for the Medical Student III Poster Session, and provide an evaluation of your work.

If your Faculty Mentor does not have a UWSOM faculty appointment, you will need a **Faculty Co-mentor** who does have a UWSOM faculty appointment. In this case, a Faculty Co-mentor is needed in order to provide assistance through UWSOM in case issues arise, and to be able to submit an evaluation of your work. If you have a Faculty Co-mentor, you will still work primarily with your Faculty Mentor and check in with your Faculty Co-mentor throughout the summer as needed. More detail on Faculty Mentors can be found here: [Information for Faculty Mentors](#).

If you undertake a project as part of a **funded program** here at UW or externally, the project may be used to fulfill the III requirement. However, you are still required to submit a III proposal for this work. If you plan to do such a program, please contact the Director of Medical Student Scholarship (somiii@uw.edu) first so we can make sure this can meet the III requirement.

Projects that will be conducted at an **international** site, and not through GHIP, will need to be reviewed by the Director of Medical Student Scholarship in the Fall prior to project proposal submission. If the Project Proposal is approved, the student **must** attend the mandatory UW Study Abroad Safety Pre-orientation. Depending on the project's program, students may also be required to attend site-specific or on-site orientations as well.

## PROPOSAL SUBMISSION

Completed proposals should be saved in **PDF format** and **must be submitted by March 2, 2020** through the ILL Canvas site. A committee of reviewers will either approve the proposal or ask that the proposal be revised. Students can expect to receive notification of the committee's decision by March 30, 2020.

## PROPOSAL EVALUATION

Project proposals are evaluated using the following eight criteria:

1. Student clearly describes the purpose of the project and a well-defined, testable hypothesis or question that is suitable for a 9-week summer project and the student's level of research experience.
2. Student demonstrates understanding of why studying this question or hypothesis is important, and clearly describes what needs to be done to complete the project.
3. Methods to be used for data collection and data analysis are clearly described and appropriate for the goal of the research. Also, the student's role in the analysis of data and interpretation of results is clearly described.
4. Student demonstrates understanding of how the results of the project will contribute to the knowledge in this field.
5. Student clearly defines their "independent role" that allows them to make "an intellectual contribution to the project." This is especially important for students who will be doing a sub-project within a larger project. The proposal must clearly define the student's discrete project for which they are personally responsible and should be independent from other post-graduate researchers including post-graduate fellows, clinical fellows, or residents.
6. Timeline is sufficiently detailed to convince the reviewer that the project will be completed within 9 weeks to ensure meeting the poster presentation requirement in Fall, 2020.
7. If applicable, the proposal describes specific plans for obtaining Human Subjects or Animal Use and Care Committee approval in advance of the project start date. Please note that projects which require approval from multiple IRBs (including international projects and those conducted at the VA, which will also require UW IRB approval) should **explicitly state** how this will be accomplished. Students are highly encouraged to obtain a free consultation with the UW IRB medical student specialist. Regardless of research location, all UWSOM medical students are considered an "entity of the University of Washington" and must follow UW IRB regulations if participating on any patient-related research projects.
8. Faculty Mentor provides a statement describing the student's expected role in the project, their plan to provide appropriate and regular supervision throughout the 9 weeks (weekly at minimum), and their signature indicating their commitment to helping the student have a successful scholarly experience.

## FINAL PRODUCT

Scholarship of Discovery students are required to present a **poster** at the Medical Student Poster Session held in the Fall of their second year. Your **Faculty Mentor** must review your poster prior printing it for the Poster Session, and complete a Faculty Mentor evaluation form of your work, also in the Fall.

Please see the [ILL website](#) for additional information. For other questions, please contact us at [somiii@uw.edu](mailto:somiii@uw.edu).

# Independent Investigative Inquiry (III) Scholarship of Discovery Project Proposal Coversheet


Please submit completed Project Proposals in **PDF format** by **March 2, 2020** through the III Canvas site. Students can expect to receive notification of the committee's decision by March 30, 2020.

**Questions?** Please contact SOM Scholarship at [somiii@uw.edu](mailto:somiii@uw.edu)


## Project Information

Title	Transition of Care from the Emergency Department for Patients with Opioid Use Disorder
Location	Harborview Medical Center
Category (Laboratory-based, Clinical research, Health Services, QI, etc)	Clinical research

## Student Information

Name	
UW Email Address	
Phone	
First-year Site	

## Faculty Mentor Information

Name & Degrees (e.g. M.D.)	
Faculty Title	
Do you hold a UWSOM Faculty appointment (yes, no)	
Department & Institution	
UW Box Number (if applicable)	
Street Address, City, State, Zip	
Email Address and Phone	

## Faculty Co-Mentor Information

(Complete this section only if your Faculty Mentor does **not** hold a UWSOM Faculty Appointment)

Name & Degrees (e.g., M.D.)	
Faculty Title	
Department & Institution	
UW Box Number (if applicable)	
Street Address, City, State, Zip	
Email Address and Phone	

## **Project Description**

Be as explicit as possible in your description. Please refer to the above instructions which outline the criteria by which applications are reviewed. Be sure to include the following in your outline of the project, not to exceed the available space (approximately 3 pages).

- 1. Background & Hypothesis**
- 2. Study Design & Methods, to include:**
  - a. Population (inclusion/exclusion criteria; recruitment procedures)*
  - b. Sample Size (ideal vs. achievable)*
  - c. Variables and how they will be measured (outcomes; exposures; potential confounders)*
  - d. Procedures for data acquisition (attach data sheets, questionnaires, etc.)*
  - e. Methods for data analysis*
- 3. Expected Significance of Results**
- 4. Clearly define your role in the project**
- 5. Preliminary Literature Search (5-10 references that address your research question)**

## **Project Description**

### **Background**

Opioid use in the United States, for both medical and non-medical purposes, has increased dramatically over the past 10 years.<sup>1</sup> With the increased prevalence of opioid use has come increased opioid dependence and unfortunate overdose. In 2017, opioids were involved in 47,600 overdose deaths, making up 67.8% of all drug overdose deaths.<sup>2</sup> The heightened prevalence of opioid use has also led to an increased number of Emergency Department (ED) visits for opioid overdose and treatment.<sup>3</sup> Despite the increase in ED visits from patients with opioid use disorder (OUD), barriers to linkage to outpatient OUD treatment post-discharge remains.<sup>3-4</sup>

The ED may be the main point of medical contact for those with OUD and linkage to potential treatment services while in the ED can provide an important opportunity for continued care. Specifically, D'Onofrio and colleagues found that patients in the ED with OUD that received ED-initiated buprenorphine were more likely to be engaged in formal addiction treatment at 30 days compared to patients who received screening and referral to treatment (SBIRT).<sup>5</sup> Patients initiated on buprenorphine were also using less illicit opioids at 30 days compared to patients in the other two groups.<sup>5</sup> While this clinical trial was extremely important, it was a single site efficacy trial and more data is needed to determine how this clinical practice change would impact care in real-world practice settings. In particular, more data is needed about patient characteristics that may be associated with OUD treatment initiation, such as concurrent methamphetamine use, housing status, and insurance status.

At Harborview Medical Center (HMC), the After Care Clinic (ACC) provides patients with OUD the opportunity for continued treatment post-discharge. The goal of our project is to determine if a formal pathway between the HMC ED and the HMC improves outcomes for patients discharged from the ED with Opioid Use Disorder. The formal pathway was implemented in May 2019, with considerable changes made to improve processes in February 2020. We hypothesize that implementation of the final pathway will result in improved transitions resulting in increased attendance at ACC appointments. We also hypothesize that certain patient characteristics will predict ACC appointment attendance and therefore improved treatment initiation and retention in treatment.

## **Study Design Methods**

This study will be a retrospective study in nature. Adult patients who present to the HMC ED, receive buprenorphine for Opioid Use Disorder (OUD) from July 1, 2019 until June 30, 2020, and are discharged to the community (e.g. not admitted to the hospital, not discharged to jail or inpatient substance use treatment) will be included in this study. Patients will be identified from the electronic medical record (EMR) and based on preliminary quality improvement data we anticipate a cohort of approximately 200-300 patients.

The primary outcome variables will be completion of initial follow-up and any subsequent follow-up visits in the HMC After Care Clinic following ED discharge for OUD. There may be potential to include completion of longterm treatment (> 30 days) in the After Care Clinic. Important covariates include age, gender, race, ethnicity, education level, diagnosis of anxiety or depression, methamphetamine use, other non-methamphetamine substance use (alcohol, cannabis, non-prescription opioids, benzodiazepines), insurance status, housing status, employment status, access to transportation, access to a cellphone, English-speaking status, and time of day of presentation to the ED.

As this will be a retrospective chart review, it is possible that some of the data will require abstraction by hand for validity. We will perform a logistic regression analysis to predict followup in ACC. Variables included in the analysis will include the covariates listed above. There may also be an opportunity to partner with the Department of Emergency Medicine Section of Population Health to understand a variety of population health topics relevant to vulnerable populations and emergency care including methamphetamine use, healthcare utilization for patients with mental health care, and social determinants of health screening in the ED.

## **Expected Significance of Results**

The results of this analysis will help to identify the factors that predict post-ED follow-up for patients with OUD, particularly the patient-based and visit-based characteristics that impact treatment outcomes. For example, patient-based characteristics such as methamphetamine use, access to stable housing, and medical insurance may all be predictors of follow-up attendance and help medical providers better understand how to incorporate these characteristics into providing tailored care. Additionally, visit-level characteristics such as the time-of-day that a

patient presents to the ED seeking care for OUD may predict the likelihood that they return to the After Care Clinic, potentially providing information about how to best provide services within the ED to assist with improved clinical attendance at After Care Care. With this information, providers may better understand how to increase the likelihood that a patient returns for outpatient care in the hopes of improving treatment outcomes.

### **Student Role**

My role in this project will be to organize and abstract the clinical data within the EMR to assess for the impact of the HMC After Care Clinic on OUD treatment outcomes. By the end of the summer, the goal is to begin work on a poster presentation and associated abstract.

## Preliminary Literature Search

1. Raub PharmD, BCPS, Joshua N., Vettese MD, Theresa E., Acute Pain Management in Hospitalized Adult Patients with Opioid Dependence: A Narrative Review and Guide for Clinicians, *Journal of Hospital Medicine*, 2017; 12(5): 375–379.
2. Centers for Disease Control and Prevention. Drug overdose deaths. <https://www.cdc.gov/drugoverdose/data/statedeaths.html>. Accessed March 8, 2020.
3. Samuels MD, MPH, Elizabeth A. et al. A Quality Framework for Emergency Department Treatment of Opioid Use Disorder, *Ann Emerg Med.*, 2019 Mar; 73(3): 237–247.
4. Duber, Herbert C. et al. Identification, Management, and Transition of Care for Patients With Opioid Use Disorder in the Emergency Department, *Ann Emerg Med.*, 2018 Oct; 72(4): 420–431.
5. D’Onofrio GD, O’Connor PG, Pantalon MV, et al. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial, *JAMA*, 2015; 313(16): 1636–1644.



## **Project Timeline**

Your project timeline should allow you to complete the project before the second year begins in September.

	<b>Tasks to be completed</b>
Week 1	Read journal articles on opioid use disorder and ED use and buprenorphine treatment for OUD and complete a preliminary literature review.
Week 2	Create a statistical analysis plan and work with ED clinical analyst to identify study cohort and data collection tools including RedCap.
Week 3	Finalize a statistical analysis plan, begin any necessary hand abstraction and chart review.
Week 4	Create a table with variables and introduction for a paper. Continue any necessary hand abstraction and chart review.
Week 5	Complete chart abstractions, begin to work with data analyst and biostatistical consultant to analyze data.
Week 6	Work with data analyst and biostatistical consultant to analyze data.
Week 7	Work with data analyst and biostatistical consultant to analyze data, fill in tables and write paper methods and results.
Week 8	Work on research poster and associated abstract.
Week 9	Work on research poster and associated abstract.

**Human and Animal Subjects**

If your project involves human subjects, your Project Proposal must address how you will obtain any required Institutional Review Board (IRB) approvals in advance of the project start date. Similarly, if the project involves animal use, this will require approval from the Animal Care and Use Committee (ACUC). You must have any required approvals granted prior to starting your project.

Students, with the assistance of their Faculty Mentors, are responsible for determining IRB requirements. Your Faculty Mentor should be well versed in what approval has already been granted and what approval is required for you to engage in the project. If you are unsure what approval is required, you can contact the UW Human Subjects Division (HSD) at [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu).

It is the responsibility of the Faculty Mentor to assist students with submission of UW and other pertinent IRB or ACUC applications as early as possible and **no later than March 2, 2020**, regardless of where research is taking place.

	Yes	No
<b>Does the project require IRB review or a determination of exemption?</b>	X	
<p><b>If yes, has the project been approved by an Institutional Review Board or has a Determination of Exemption by HSD?</b></p> <p><input type="checkbox"/> <b>Yes</b>, this project has been granted IRB approval or received a determination of exemption under study # _____.</p> <p><input checked="" type="checkbox"/> <b>No</b>, this project has not yet been approved. The following plan for obtaining required IRB approvals is in place: Dr. Whiteside will work with Layla Anderson (Clinical Research Manager in the Department of Emergency Medicine) to complete an IRB for permission to review this retrospective EMR data. We anticipate this will be done by May 1<sup>st</sup>.</p>		
<b>Are experiments with vertebrate animals involved?</b>		X
<p><b>If yes, has the animal protocol been approved by the appropriate Animal Use and Care Committee?</b></p> <p><input type="checkbox"/> <b>Yes</b>, this project has been granted IACUC approval under study # _____.</p> <p><input type="checkbox"/> <b>No</b>, this project has not yet been approved. The following plan for approval is in place:</p>		


**Faculty Mentor Statement**

Students are asked to work with a faculty member who may be any UWSOM faculty member with an Affiliate, Clinical, or Regular faculty appointment, including those at the Instructor level. Fellows and residents do **not** hold Faculty appointments, and are **not** eligible to be a research mentor or co-mentor. If the Faculty Mentor **does not** have a UWSOM faculty appointment, the student will need a **Faculty Co-mentor** who **does** have a UWSOM faculty appointment. The Faculty Mentor must be experienced and familiar with the project topic and methods used in the study. The Faculty Mentor’s role is to help the student plan the study, regularly meet with the student (weekly at minimum) during the execution of the project, review and sign-off on the final poster, and submit an evaluation of the student’s work.

**In the space below, please provide a brief paragraph on:** 1) your willingness to mentor the student, 2) the role the student will play in the project and how you will ensure this is an independent project 3) your evaluation of the student’s ability to carry out the work, and 4) your agreement with the project proposal and timeline above. The application will be considered incomplete if this information is not included.

I am excited and pleased to mentor [REDACTED] on this research project that includes a retrospective review of data from the electronic medical record (EMR) to determine factors associated with buprenorphine treatment initiation and linkage to outpatient treatment for patients with opioid use disorder who use the Emergency Department for care. I have previously mentored students and learners and have a track record of assisting students from project beginning to publication. This project extends from current quality improvement work I am doing in coordination with collaborators in General Internal Medicine (GIM) and Lauren Nguyen will take the lead on this project with support from me, my collaborators and the Department of Emergency Medicine. She has a tremendous amount of research experience and comes with a great amount of enthusiasm and passion for this project and topic and I believe she is extremely capable of completing this project. As this project relies on EMR data, I have no doubt the project can be completed during the existing timeline and I believe it is feasible and important work. Overall, I am very excited to work with [REDACTED] on this project and believe that the results will be timely and clinically relevant.

**Signatures**

<b>Signature of Student</b>		
<b>Signature of Faculty Mentor</b>		
<b>Signature of Faculty Co-Mentor</b> (if applicable)		
<b>Date</b>		

**QUESTIONS? Please contact:**  
SOM Scholarship at [somiii@uw.edu](mailto:somiii@uw.edu)