Summer Student Research Program
Project Description

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PROJECT TITLE (200 Characters max):
Safety and Efficacy of High Dose BUP Initiation in Fentanyl Positive Emergency Department Patients

HYPOTHESIS:
The main hypothesis is that high dose BUP (32mg) delivered over 30-60 minutes will be safe and well tolerated and that participants in the high dose initiation arm will have at least a 15% increased proportion engage in comprehensive addiction care by 7-days post ED visit than those receiving standard initiation.

PROJECT DESCRIPTION **(Include design, methodology, data collection, techniques, data analysis to be employed and evaluation and interpretation methodology)**

Study Description: Fentanyl positive patients in withdrawal coming to the emergency department (ED) are a highly vulnerable population. This project, involving two distinct clinical trials, tests whether initiation to a higher than currently recommended buprenorphine (BUP) initiation dose is safe and can improve the proportion of patients who engage in comprehensive addiction services within 7-days of initiation. Trial 1 is a head-to-head comparison of the safety, tolerability and feasibility of high dose BUP initiation (32 mg). The study involves two cohorts, (1) a 12mg cohort (standard) to determine baseline data and (2) a 32 mg (high dose) cohort. If the 32mg is intolerable, a 24 mg dose may be evaluated. Trial 2 is a small pilot multicenter randomized, double blinded, clinical trial in 80 participants (randomized 1:1) that will provide preliminary information on efficacy with the primary outcome being engagement in comprehensive addiction treatment 7-days post BUP initiation. In collaboration with NIDA, we have determined that there must be a minimum increase in engagement in comprehensive addiction treatment of 15% at 7-days in the high dose initiation group to justify a larger future clinical trial (predefined margin). Objectives: Previous retrospective studies have demonstrated the safety and tolerability of high dose BUP initiation, but systematic prospective studies are lacking. Furthermore, high dose BUP initiation has not been examined for clinical efficacy with regard to engagement in comprehensive addiction care post-initiation compared to standard initiation protocols. Thus, the primary objectives of the two trials described in this protocol are to: Trial 1: Prospectively determine the safety, tolerability and feasibility of high dose BUP initiation in a single ED as assessed by the number of treatment-related adverse events grade 3 or above, precipitated withdrawal events, or respiratory depression events. The main hypothesis is that high dose BUP (32mg) delivered over 30-60 minutes will be safe and well tolerated. Trial 2: To compare the effectiveness of high dose BUP initiation from Trial 1 to standard dose BUP initiation on the primary outcome of engagement in comprehensive addiction treatment at 7-days. The main hypothesis is that participants in the high dose initiation arm will have at least a 15% increased proportion engage in comprehensive addiction care by 7-days post ED visit than those receiving standard initiation.

SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:

O'Conor C, Farhi S, Cowan E, Fitzgerald R. Inpatient initiation of long-acting injectable buprenorphine at a community hospital: A retrospective case series. J Addict Dis. 2024 Sep 1:1-7. doi: 10.1080/10550887.2024.2391145. Epub ahead of print. PMID: 39219151.

Goldberg LA, Chang TE, Freeman R, Welch AE, Jeffers A, Kepler KL, Chambless D, Wittman I, Cowan E, Shelley D, McNeely J, Doran KM. Implementation of a peer-delivered opioid overdose response initiative in New York City emergency departments: Insight from multi-stakeholder qualitative interviews. J Subst Use Addict Treat. 2025 Jan;168:209542. doi: 10.1016/j.josat.2024.209542. Epub 2024 Oct 21. PMID: 39442627.

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D'Onofrio G, Herring AA, Perrone J, Hawk K, Samuels EA, Cowan E, Anderson E, McCormack R, Huntley K, Owens P, Martel S, Schactman M, Lofwall MR, Walsh SL, Dziura J, Fiellin DA. Extended-Release 7-Day Injectable Buprenorphine for Patients With Minimal to Mild Opioid Withdrawal. JAMA Netw Open. 2024 Jul 1;7(7). PMID: 38976265.

Cowan E, Perrone J, Dziura J, Edelman EJ, Hawk K, Herring A, McCormack R, Murphy A, Phadke M, Fiellin D, D'Onofrio, G. Urine Toxicology Profiles of Emergency Department Patient with Untreated Opioid Use Disorder: A Multi-Site View. The Journal of Emergency Medicine, 2023, ISSN 0736-4679, https://doi.org/10.1016/j.jemermed.2023.06.007.

Doran KM, Welch AE, Jeffers A, Kepler KL, Chambless D, Cowan E, Wittman I, Regina A, Chang TE, Parraga S, Tapia J. Study protocol for a multisite randomized controlled trial of a peer navigator intervention for emergency department patients with nonfatal opioid overdose. Contemporary Clinical Trials. 2023 Feb 4:107111. doi: 10.1016/j.cct.2023.107111. PMID: 36746325.

D'Onofrio G, Edelman EJ, Hawk KF, Chawarski MC, Pantalon MV, Owens PH, Martel SH, Rothman R, Saheed M, Schwartz RP, Cowan E, Richardson L, Salsitz E, Lyons MS, Freiermuth C, Wilder C, Whiteside L, Tsui JI, Klein JW, Coupet E, O'Connor PG, Matthews AG, Murphy SM, Huntley K, Fiellin DA. Implementation Facilitation to Promote Emergency Department-Initiated Buprenorphine for Opioid Use Disorder. JAMA Netw Open. 2023 Apr 3;6(4):e235439. PMID: 37017967; PMCID: PMC10077107.

Justen MA, Edelman EJ, Chawarski M, Coupet E, Cowan E, Lyons M, Owens P, Martel S, Richardson L, Rothman R, Whiteside L, O'Connor P, Zahn. E, D'Onofrio G, Fiellin DA, Hawk KF. Perspectives on and Experiences of Emergency Department-Initiated Buprenorphine among Clinical Pharmacists: A Multi-Site Qualitative Study. Journal of Substance Use and Addiction Treatment. Accepted 05/23.

Cowan E, Perrone J, Bernstein SL, Coupet E Jr, Fiellin DA, Hawk K, Herring A, Huntley K, McCormack R, Venkatesh A, D'Onofrio G. National Institute on Drug Abuse Clinical Trials Network Meeting Report: Advancing Emergency Department Initiation of Buprenorphine for Opioid Use Disorder. Ann Emerg Med. 2023 May Epub ahead of print. PMID: 37178101.

THIS PROJECT IS: ☒ **Clinical** ☐ **Laboratory** ☐ **Behavioral** ☐ **Other**

THIS PROJECT IS CANCER-RELATED ☐
Please explain Cancer relevance

THIS PROJECT IS HEART, LUNG & BLOOD- RELATED ☐
Please explain Heart, Lung, Blood relevance

THIS PROJECT INVOLVE RADIOISOTOPES? ☐

THIS PROJECT INVOLVES THE USE OF ANIMALS ☐
PENDING ☐ **APPROVED** ☐ **IACUC PROTOCOL #**

THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS? ☒
PENDING ☐ **APPROVED** ☐ **IRB PROTOCOL # M Pro2024002445**

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS	☒	ENTERING FRESHMAN	☐
SOPHMORES	☒	ALL STUDENTS	☐

THIS PROJECT IS WORK-STUDY: **Yes** ☐ **or** **No** ☒

THIS PROJECT WILL BE POSTED DURING ACADEMIC YEAR

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FOR INTERESTED VOLUNTEERS: **Yes** ☒ **or** **No** ☐

WHAT WILL THE STUDENT LEARN FROM THIS EXPERIENCE?

The student will learn about clinical research trials, including screening, enrollment, informed consent, and follow-ups. They will gain insight into the structure, processes, and ethical considerations of clinical trials, understanding how medical research is conducted, including the phases of trials, protocols, and data collection. Volunteering in a clinical setting also offers the opportunity to collaborate with researchers, healthcare providers, and patients. Cross-disciplinary teamwork is a vital skill that will benefit students in any future career. Additionally, students will learn about opioid use disorder, medications for opioid use disorder, and harm reduction techniques. They will have the chance to interact with patients, gaining valuable experience in patient care and the importance of clear communication and empathy. Through this experience, students will not only enhance their technical and scientific knowledge but also develop crucial skills like communication, attention to detail, and documentation—skills that are essential for their future careers in healthcare or research.