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Study Assessing the Effectiveness of Overdose Prevention Centers Through Evaluation Research

SAFER Evaluation Engagement Policy

INTRODUCTION

The conduct and execution of our overdose prevention center (OPC) evaluation in New York City and Rhode Island is guided by our research teams' missions, values, and goals. Specifically, we hold ourselves to the highest standards of academic integrity and are committed to carrying out an evaluation of the highest rigor and caliber. Furthermore, we strive to adopt best practices in community-engaged research methods, prioritize meaningful stakeholder engagement, and seek to provide opportunities for people with lived experience to participate in the evaluation, including but not limited to an active, cross-site community advisory board (CAB).

We ask that all staff, faculty, students, and postdoctoral research associates collaborating on the evaluation agree to adhere to the terms of this policy, which sets forth the terms and conditions for the use of data and all research materials, as well as all products related to this project. For our purposes, the term 'data and materials' includes all primary and secondary data collected as part of this evaluation, including field notes, qualitative interview transcripts, administrative data, and cohort survey data. This term also includes all study instruments, protocols, and policies, and dissemination products.

REQUEST TO COLLABORATE

A request to collaborate on the OPC evaluation should be made to the study co-principal investigators, Drs. Cerdá and Marshall. If a collaborator (i.e., an unpaid role) or current co-investigator (i.e., a person contributing measurable percent effort) wishes to lead a publication, conference abstract, or other academic product, they must first complete a project proposal using the approved template. Researchers interested in submitting a grant application that leverage SAFER study infrastructure, data, or community relationships should also submit a proposal using the template. Once completed, the project proposal should be submitted to a project manager at either site, who will then circulate it to the PIs and co-investigators for review. The project managers will be responsible for tracking all project proposals and data & materials requests. Next:

1. The SAFER Internal Advisory Board will have two weeks to provide feedback on the proposal and may elect to participate in the writing group (i.e., a subset of co-investigators who are interested in co-authoring the product);
2. The lead author may be asked to present their proposal at a biweekly investigator's meeting;

3. Based on feedback from the co-investigators and (in certain cases) discussion at an investigator's meeting, the Internal Advisory Board (see below) will then approve or reject* the proposal;
4. If approved, a project manager will work with the lead author and other research staff (e.g., the data manager, biostatistician) to provide access to data & materials necessary to complete the work (see Use of Materials below);
5. The lead author completes the scope of work;
6. The lead author then circulates the work to the writing group for review. The writing group should be given at least 30 days to review all products, including conference abstracts;
7. The lead author must adhere to the team's authorship policy, including pre-dissemination review of all outputs;
8. The final draft will be circulated to the Internal Advisory Board (see below), with an author list and order finalized by the senior/corresponding author in accordance with the team authorship policy;
9. Once pre-dissemination review is complete and approval from the Internal Advisory Board has been obtained, the lead author can submit the product for peer review.

We expect that lead authors will submit their work for publication within 12 months of submitting a proposal to the project manager. The co-principal investigators reserve the right to re-assign scientific products that are languishing and are not submitted in a reasonable timeframe.

* A proposal may be rejected for various reasons, including a poor quality study design, lack of agreement and/or insufficient buy-in from the co-investigators, or risk of duplication with a previously approved proposal. For example, this would be done to avoid scenarios where a doctoral student—working on a previously approved thesis paper—is 'scooped' by another collaborator or co-investigator. During the approval process, the co-principal investigators may also solicit input from the Internal Advisory Board or CAB to determine the appropriateness, academic value, and rigor of the planned work.

USE OF MATERIALS

This is a high-visibility project of national public health importance, and we are often working with sensitive data containing personal health information (PHI). We make every effort to ensure that study data & materials are not used in inappropriate ways, or in a manner that may

compromise participant confidentiality & privacy. For these reasons, the lead author agrees to use the data & materials only in publications or analyses that have been previously approved by the co-principal investigators. The data & materials will be distributed to lead authors only for the purposes of carrying out the work that was approved, and the lead author agrees not to use the data & materials for any other purpose. The lead author further agrees not to share or re-circulate the data & materials with anyone outside the research team, unless that person has signed this agreement and is a co-author on an approved manuscript, abstract, or analysis. Finally, the lead author must adhere to protocols determined necessary by the data manager for any particular project, including the use of Stronghold or another secure computing environment. Once the project is complete, the lead author shall return all study data & materials to a project manager.

INTERNAL ADVISORY BOARD

The SAFER Internal Advisory Board is responsible for reviewing and approving all academic products, including but not limited to manuscripts and conference abstracts. The board aims to provide approval and/or additional feedback to lead authors within two weeks of a submission. The Internal Advisory Board will consist of the following:

- The leadership team (co-principal investigators and a project director from each site)
- A member of senior leadership from each participating OPC
- The senior biostatistician
- A qualitative research team lead
- The health economics research lead

Committee members will serve annual terms and membership may be refreshed/rotated annually depending on project needs.

TERMINATION OF AGREEMENT

If the lead author is no longer involved in the project they agree to remain bound by this agreement. As an example, if a lead ends their involvement with the OPC evaluation research team, they would not be able to use any data & materials derived from the project for subsequent research unless it was previously approved.

The co-principal investigators reserve the right to revoke access to study data and materials if the lead author does not adhere to these guidelines. The co-principal investigators also reserve the right to re-assign the work to another lead author in accordance with the team's authorship policy.

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All questions and concerns regarding the team's authorship policy can be directed towards the team's principal investigators, Drs. Brandon Marshall (brandon_marshall@brown.edu) or Magdalena Cerdá (magdalena.cerda@nyulangone.org).

By signing below, I acknowledge that I have read and understand this agreement and agree to be bound by its terms:

_____ _____

(Signature) (Date)

Revised July 31st, 2023