REQUEST FOR PROPOSALS

Improving the Treatment of Opioid Use Disorders

The Laura and John Arnold Foundation’s (LJAF) core objective is to address our nation’s most pressing and persistent challenges using evidence-based, multi-disciplinary approaches. LJAF is seeking proposals from organizations with ideas for evaluating addiction treatment programs and strategies for people with opioid use disorders. Projects may be focused on rigorously evaluating existing treatment programs, testing new approaches to treatment, and re-orienting government spending around effective programs that demonstrate measurable results. This request is part of an effort to accelerate the adoption of evidence-based approaches to treating opioid addiction.

Background information

Cities and towns across the country are facing an opioid addiction epidemic. More than 28,000 people died from opioid overdoses in 2014, and more than 2 million individuals now suffer from an opioid use disorder. This creates serious health, social, and financial consequences for individuals as well as significant costs to society, including an increase in crime and health care spending.

Many communities are seeking promising solutions and have implemented a number of different programs in an effort to treat individuals with opioid use disorders. However, the majority of federal, state, and local funding for opioid addiction treatment is allocated to programs that are not based on evidence and have not been rigorously evaluated. Thus, we know very little about whether the treatment programs provided by governments and health care practices work as intended. Although a growing body of research suggests that medication-assisted treatment (MAT) combined with behavioral interventions could be an effective method of treating individuals with opioid use disorders, further study is needed to determine if and how these programs should be expanded and scaled to help people with different needs.

Project categories

LJAF is seeking proposals for projects that fall under the following categories:

I. Evaluations of interventions funded by governments or other entities to treat opioid use disorders

These proposals should address important research questions that can inform decisions about the efficacy and cost effectiveness of traditional and alternative treatment programs and service delivery approaches. Proposals should be developed by researchers working in close partnership with practitioners and government agencies. When possible, LJAF encourages research proposals that use administrative data to measure important outcomes (e.g., patient health, substance use, emergency room visits, criminal recidivism, and long-term measures of well-being such as education and employment) in addition to measuring how the program affects costs.
LJAF is interested in studies that will improve understanding of people with opioid use disorder and their families (e.g., individuals’ ability to obtain and maintain employment, manage money, and maintain trusted relationships) as well as the treatment strategies and other supports that can help them achieve their goals.

LJAF invites evaluation proposals in two tiers.

- **Randomized Controlled Trial (RCT) Tier:** Studies using an RCT design should address the criteria and follow the submission instructions in Appendix A.

- **Innovation Tier:** Proposals that will use other evaluation methodologies should address the criteria in Appendix B for feasibility studies that can translate to follow-up impact studies. If the applicant demonstrates that a follow-up study could not be carried out using an RCT design, the applicant should describe an alternative strategy for a follow-up evaluation that uses the most rigorous research design feasible. For examples of non-experimental study designs and their appropriate applications, please refer to the guidelines published by the Society of Prevention Research and the UNICEF Office of Research. For additional guidance on which non-experimental methods yield credible evidence, see “Which Comparison-Group (“Quasi-Experimental”) Study Designs Are Most Likely to Produce Valid Estimates of a Program’s Impact?”

II. Innovations in government program design, delivery systems, and infrastructure to build rigorous evidence, redirect spending, and improve access to proven treatment programs

These projects should be developed by partnerships involving government decision makers, practitioners, and researchers. Funding will be provided to support study design, infrastructure, and system innovations rather than direct service provision. Proposals may seek planning grants or full implementation grants that address one or more of the following.

*Government Financing Structures Designed to Accelerate Evidence Generation:*

- Innovative grant-making and procurement models that incentivize grantees and providers receiving government funds to (1) use strategies that are backed by the best available evidence of effectiveness and (2) rigorously test promising approaches to improve impact and cost-effectiveness. These may include Pay for Success and other pay-for-performance contracts; grants that use a “tiered evidence” design; grants that give preference to projects that use rigorous evidence and participate in a rigorous evaluation; or waiver demonstrations that provide flexibility to blend funding or test approaches that were not envisioned in programmatic statutes and regulations. Such program models could be created by federal, state, local, or tribal governments.

- Innovative strategies for dramatically increasing the number of providers and sites that participate in rigorous evaluations. For example, a technology platform might be developed to allow providers to connect to each other and high-quality researchers wishing to test a specific bundle of services using rigorous, low-cost evaluation designs. Government funders could clarify that program funds can be used for rigorous, low-cost evaluations using administrative data.
Setting the Stage to Generate Rigorous Evidence

- Learning agendas developed by federal, state, and/or local government decision makers and researchers that (1) identify critical knowledge gaps; (2) establish evaluation priorities, key research questions, and the most feasible and appropriate rigorous evaluation designs; and (3) recruit highly qualified researchers to work with government agencies and providers to conduct evaluations that are independent, rigorous, and transparent.

- Improved capacity to link and share data about individuals—with necessary privacy protections in place—in order to measure progress against baselines and comparison groups and to conduct rigorous, low-cost evaluations about the impacts and cost-effectiveness of varying treatment approaches. For example, projects could leverage reliable administrative data held by health care providers, insurers, the pharmaceutical industry, and government, including national data sets such as those held by the Centers for Medicare and Medicaid Services and the U.S. Census Bureau.

Dissemination and Adoption of Evidence-Based Strategies

- Improved knowledge dissemination to provide rigorous, actionable information to government decision makers, practitioners, and consumers that would help them make better choices based on evidence. For example, a project could augment the information about evidence-based programs available through the U.S. Department of Health and Human Services’ National Registry of Evidence-Based Programs in ways that emphasize treatment models with the strongest evidence of impact and the steps that would be necessary for effective implementation.

Systemic Changes to Improve Access to Evidence-Based Treatment

- Innovative models of service delivery that dramatically increase access to evidence-based treatment options or improve the infrastructure of pre-existing care models. For example, a project could propose a new model of coordinated care that makes it easier for patients in rural areas to access quality treatment at different stages of the MAT process.

Other

- Other strategies that could significantly advance learning and adoption of evidence-based practices in treating opioid use disorder. These could include white papers or roundtables that have a high probability of altering government policies or practices that now impede expansion of evidence-based treatment of opioid use disorder. For example, a group of government and non-government thought leaders could develop a blueprint to explain how government, philanthropy, and the private sector could collaborate to ensure that every person with opioid use disorder has access to evidence-based treatment within five years.

Proposals in category II should address the selection criteria outlined in Appendix C.
Appendix A: Part I RCT Tier Submission Criteria

Improving the Treatment of Opioid Use Disorders

Randomized Controlled Trial (RCT) Tier

RCT Tier Criteria

The Laura and John Arnold Foundation’s (LJAF) Evidence-Based Innovation team invites grant applications to conduct randomized controlled trials (RCTs) of opioid use disorder treatment programs for which:

(i) LJAF will fund the RCT, and government or another entity will fund the program’s delivery; and

(ii) The RCT meets the additional selection criteria set out below.

Our goal in funding such RCTs is to build the body of programs rigorously shown to produce sizable, sustained benefits to participants or society, and to do so in a cost-efficient manner by leveraging program funds contributed by government, philanthropic foundations, or other funders.

We ask applicants first to submit a letter of interest (maximum three pages). Applicants whose letters are reviewed favorably will be invited to submit a full proposal (maximum six pages).

I. Selection Criteria:

Applicants should please address the following four criteria in a letter of interest:

- **PROGRAM FUNDER**
  Will the proposed RCT evaluate a program whose delivery is paid for by another funder, and does that funder, or do other essential parties, agree to the study? To verify such agreement(s), the reviewers will look for attached letters or other communications showing that the necessary parties (e.g., program funder and/or program provider) assent to the study, including random assignment. Such agreement(s) may be tentative at the time that the letter of interest is submitted, but should be finalized before submission of the full proposal. We especially encourage proposals in which the necessary parties not only assent to the study but also provide a credible description of how they or others would use the study findings to inform program or policy decisions.

- **IMPORTANCE**
  Does the proposed evaluation involve a program:

  - That is backed by highly-promising prior evidence, suggesting it could produce sizable impacts on outcomes of recognized policy importance such as public safety, public health, cost of treatment, or fairness in the provision of services? For example, we specifically encourage applications seeking to replicate findings from prior rigorous evaluations that are especially promising but not yet conclusive (e.g., due to only short-term follow-up, a single-site study design, or well-matched, but not randomized, comparison groups). As a threshold condition for “highly promising” evidence, applicants should show that the program can be, or (preferably) has been, successfully delivered under real-world implementation conditions.

- or -
• For which there are other compelling reasons to evaluate its effectiveness—e.g., it is, or soon will be, widely implemented with significant taxpayer investment, and its impact on its targeted outcomes is currently unknown.

Please note that, to meet this criterion, it is not sufficient to establish that the study addresses an important problem; applicants must also present compelling reasons to evaluate the specific program.

➢ EXPERIENCED RESEARCHER

Does the applicant’s team include at least one researcher in a key substantive role who has previously carried out a well-conducted RCT? A well-conducted RCT is characterized, for example, by low sample attrition, sufficient sample size, close adherence to random assignment, and valid outcome measures and statistical analyses. To address this criterion, applicants should submit reports from prior RCTs that the researcher has conducted. (Please send the full study reports as email attachments to the proposal—no more than two reports in all.) Reviewers will rely primarily on these reports in assessing this selection criterion.

➢ STUDY DESIGN

Is the applicant’s proposed RCT design valid? In other words, does it have a sufficiently large sample (as shown through a power analysis) and other elements needed to generate credible evidence about the program’s impact on one or more targeted outcomes of high policy importance? We strongly encourage designs that measure such outcomes in both the short and longer term, as appropriate for the type of program and study, to determine whether the effects endure long enough to constitute meaningful improvement in people’s lives. Reviewers, in assessing an applicant’s proposed design, will use Key Items to Get Right When Conducting RCTs of Social Programs as a reference.

Applicants, as part of their discussion of this criterion, should specify the study’s primary outcome(s) of interest; how they will measure the outcome(s) and over what length of time; and what analyses they plan to conduct (e.g., any subgroups to be examined, regression methods to be used).

A. Other items to include:

1. Applicants should specify the amount of funding requested. To reduce study costs, we encourage the use of administrative data (e.g., wage records, criminal arrest records) to measure key study outcomes, wherever feasible, in lieu of more expensive original data collection. In addition, if the applicant proposes any implementation research to complement the RCT, we suggest streamlined approaches that do not greatly increase the overall study cost. If additional funding from other sources is needed to carry out the study, we request that the applicant’s budget show (i) the total study cost, and (ii) the portion of that cost to be covered by LJAF. The applicant should also include an attached letter or other communication showing that the additional funding will be in place prior to LJAF’s grant award.

LJAF allows for project-related overhead expenses such as salaries and benefits of administrative staff, equipment, supplies, and travel to be included in direct costs; however, LJAF will only provide funding for indirect costs, up to a 10% limit, if extenuating circumstances exist and have been approved by LJAF prior to submission of an invited full proposal through the RFP process.
2. Applicants should specify the proposed recipient of the grant award, which LJAF generally expects to be a tax-exempt organization (e.g., nonprofit organization, university, or governmental unit). If an organization is not tax-exempt and wishes to apply, please contact the LJAF team (see contact information below).

3. Applicants should briefly address how their study meets recognized ethical standards for research with human subjects.

II. What to Expect in the Grant Agreement:
We will ask awardees, as a condition of their award, to:

- Pre-register the study on the Open Science Framework (OSF) website and, prior to commencement of the study, upload a copy of the research and analysis plan described in their proposal.

- Provide us with brief phone or email updates on the study’s progress on a periodic basis, and before making any key decisions that could materially affect the study’s design or implementation.

- Submit concise reports on the impact findings at appropriate intervals. These reports should make it easy for readers to see the study’s main results and gauge their credibility (e.g., by showing the similarity of the treatment and control groups in pre-program characteristics, the amount of sample attrition, and the statistical significance of the impact findings).

- Make their datasets and related materials (e.g., survey instruments, code used to clean and analyze datasets) publicly available on the OSF site. We ask applicants to do this within one year of the last data collection, and only to the extent allowed under any confidentiality/privacy protections.

[Note: The above list previews the main items in the grant agreement, but is not an exhaustive list of the conditions of the award.]

Submission guidelines

Proposals for all project categories should meet the following guidelines in no more than three pages total:

- Address each of the selection criteria in the relevant appendix for the appropriate project category;
- Be single- or double-spaced and use an 11-point font or larger;
- Specify the proposed recipient of the grant award, which LJAF generally expects to be a tax-exempt organization (e.g., public charity or governmental unit); and
- Specify the amount of funding required to conduct the proposed initiative. A budget may be submitted as an attachment to the proposal and will not count toward the three-page limit.

Proposals will be accepted through Dec. 15, 2016. Please direct letters and questions to Evidence-BasedInnovationLOI@arnoldfoundation.org. If LJAF determines that your proposal meets the criteria outlined above, you may be asked to submit a full proposal.
**Additional information**

LJAF grant funds may only be used for charitable, educational, and/or scientific purposes. LJAF does not fund efforts to influence legislation, to intervene in political elections or campaigns, to promote propaganda, or to conduct voter registration drives. LJAF does not make grants or loans to individuals and does not directly fund scholarships, fellowships, or prizes.
Appendix B: Part I Innovation Tier Submission Criteria

**Improving the Treatment of Opioid Use Disorders**

*Innovation Tier*

**Evaluations of Innovative Proof of Concept Projects That Could Advance to Randomized Controlled Trials**

**Innovation Tier Criteria**

Many potential treatment models for opioid use disorders have yet to be implemented or have been implemented in limited settings. We seek proposals for implementing innovative treatment models in order to help them transition from the “strong concept” stage to readiness for an impact evaluation. These feasibility studies will provide an opportunity to pilot test new ideas on a small or modest scale in the real world.

We ask applicants first to submit a letter of interest (maximum three pages). Applicants whose letters are reviewed favorably will be invited to submit a full proposal (maximum six pages).

I. **Selection Criteria:**

- **IMPORTANCE**
  
  Is the applicant proposing to implement an intervention:

  - That **targets outcomes of recognized policy importance** such as public safety, public health, cost of treatment, or fairness in the provision of services? Intermediate outcomes, such as number of individuals treated or satisfied with treatment, must be supplemented by measures of ultimate outcomes of interest, and

  - That is supported by compelling logic, which is informed by the most relevant and rigorous evidence available, that the intervention has the potential to produce large **impacts on the target area?** For example, the applicant might (the following examples are for illustrative purposes only):
    
    o Review the literature on a treatment model for opioid use disorder and its success in reducing recidivism and improving health outcomes for a certain population, and propose to test a new form of model that combines the most promising elements of previous models with new therapies tailored to address specific problems that have limited success in the past;
    
    o Present evidence that a certain treatment model is highly effective but not adequately targeted to the population most likely to benefit, as well as convincing logic that a new mechanism can improve the targeting of services; or
    
    o Present rigorous experimental evidence that an intervention improves health outcomes for one population (*e.g.*, adults with opioid use disorder) and propose to develop and test an adapted version of that intervention for another population (*e.g.*, teenagers with opioid use disorder).
STUDY DESIGN
Will the applicant’s proposed feasibility study design:

- Deliver an intervention at a small or modest scale in a real world context (e.g., treatment facility, drug court, community center, or hospital as opposed to a laboratory context)?

- Document the key elements of the intervention (including the program model, training, supervision, and cost) so that future practitioners and researchers will be able to replicate it?

- Collect data to show whether the intervention was successfully delivered, in close adherence to its key elements (e.g., what tasks were performed to implement the intervention and how closely did those tasks match the model, which people were involved in each intervention task, and how widespread/intense was the intervention among the population targeted; for service-delivery interventions, the data should show who showed up, who received the targeted amount of services, and who completed the program)?

- Measure proximal outcomes to assess whether the intervention may be affecting the elements of behavior the intervention seeks to change (e.g., attendance at counseling sessions, patient adherence to a course of treatment)?

- Demonstrate the ability to measure ultimate outcomes of interest for those receiving the intervention that could be used to compare a treatment and control group if the project goes forward to an RCT or rigorous Quasi-Experimental Design (QED) (e.g., structures to document recidivism, health, and employment for the individuals treated by the intervention)?

TEAM
Does the applicant’s team include all parties needed to conduct a feasibility study that can transition to an RCT or rigorous QED? Such a team should include:

- An experienced practitioner or agency leader who has successfully implemented an innovative intervention in a real world setting, with documented adherence to the intervention’s key elements.

- One or more researchers who have previously (1) conducted implementation studies and documented key elements of a program model for use in replication studies; and (2) carried out a well-conducted RCT (an RCT with low sample attrition, sufficient sample size, and valid outcome measures and statistical analyses) or rigorous QED and who will help the team to design the feasibility study so that it can flow seamlessly into an RCT or rigorous QED.

- Personnel familiar with agency administrative data who can assist researchers in accessing and understanding the data, if such data will ultimately be needed to measure outcomes.

Note: Applicants may be asked to verify the existence of such a team with attached letters or other communication showing, for example, that (a) an appropriate agency that delivers the intervention has agreed to participate in the study; and (b) a data agency has agreed to provide the researcher(s) with access to the administrative data needed to measure study outcomes.
STRATEGY FOR FOLLOW-UP RCT OR RIGOROUS QED

Does the applicant’s proposal describe a strategy for transitioning to an RCT or rigorous QED, including a statement of approval from the parties mentioned above that an RCT or rigorous QED is possible given successful implementation?

- For a proposal to conduct a follow-up study using methodology less rigorous than an RCT, the applicant’s proposal should address why an RCT would not be feasible or appropriate. Since the goal of a feasibility study is to transition to an impact evaluation that can produce credible evidence (or to rule out the need for such a study), this section will be critically important for reviewers.

II. What to Expect in the Grant Agreement

We will ask awardees, as a condition of their award, to:

- **Pre-register the study on the Open Science Framework (OSF) website** and, prior to commencement of the study, upload a copy of the research and analysis plan described in their proposal.

- **Provide us with brief phone or email updates on the study’s progress on a periodic basis, and before making any key decisions that could materially affect the study’s design or implementation.**

- **Submit concise reports on the impact findings at appropriate intervals.** These reports should make it easy for readers to see the study’s main results and gauge their credibility (e.g., by showing the similarity of the treatment and control groups in pre-program characteristics, the amount of sample attrition, and the statistical significance of the impact findings).

- and -

- **Make their datasets and related materials (e.g., survey instruments, code used to clean and analyze datasets) publicly available on the OSF site.** We ask applicants to do this within one year of the last data collection, and only to the extent allowed under any confidentiality/privacy protections.

[Note: The above list previews the main items in the grant agreement, but is not an exhaustive list of the conditions of the award.]

**Submission guidelines**

Proposals for all project categories should meet the following guidelines **in no more than three pages total**:

- Address each of the selection criteria in the relevant appendix for the appropriate project category;
- Be single- or double-spaced and use an 11-point font or larger;
- Specify the proposed recipient of the grant award, which LJAF generally expects to be a tax-exempt organization (e.g., public charity or governmental unit); and
- Specify the amount of funding required to conduct the proposed initiative. A budget may be submitted as an attachment to the proposal and will not count toward the three-page limit.

Proposals will be accepted on a rolling basis through Dec. 15, 2016. Please direct letters and questions to Evidence-BasedInnovationLOI@arnoldfoundation.org. If LJAF determines that your proposal meets the criteria outlined above, you may be asked to submit a full proposal.
**Additional information**

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Appendix C: Part II Submission Criteria

**Improving the Treatment of Opioid Use Disorders**

*Innovations in government program design, delivery systems, and infrastructure to build rigorous evidence, redirect spending, and improve access to proven treatment programs*

**Part II Criteria**

These projects should be developed by partnerships involving government decision makers, practitioners, and researchers. Funding will be provided to support study design, infrastructure, and system innovations rather than direct service provision. Proposals may seek planning grants or full implementation grants that address one or more of the following:

1. Government financing structures designed to accelerate evidence generation
2. Setting the stage to generate rigorous evidence
3. Dissemination and adoption of evidence-based strategies
4. Systemic changes to improve access to evidence-based treatment
5. Other strategies that could significantly advance learning and adoption of evidence-based practices in treating opioid use disorder.

We ask applicants first to submit a letter of interest (maximum three pages). Applicants whose letters are reviewed favorably will be invited to submit a full proposal (maximum six pages).

**Selection Criteria:**

Proposals in category II should address the following selection criteria:

- **POLICY RATIONALE**
  What specific problem of recognized policy importance is your project addressing? How does that problem significantly impact a large or underserved population? What is the likelihood that your project will meaningfully impact policy?

- **THEORY OF CHANGE**
  How will your proposal lead to a beneficial change in policy or practice? What additional steps will be needed after the conclusion of your project to ensure impact? We are particularly interested in projects that have the:
  - Potential to build rigorous evidence about what treatment strategies achieve the best outcomes for individuals and taxpayers (e.g., patient health, emergency room visits, criminal recidivism, and measures of sustained well-being such as employment and education) and at what cost;
  - Potential to enable and incentivize government decision makers, providers, and practitioners to continuously evaluate and improve treatment programs; or
  - Potential to result in shifts of taxpayer resources from less effective to more effective practices.
➢ **ORGANIZATIONAL CAPACITY**
   Do you have the internal capacity to carry out your theory of change? Are you best positioned to address the problem? Who are the key players on your team?

➢ **EXTERNAL SUPPORT AND PARTNERSHIPS**
   Who are your collaborators and supporters in government and the research community? Have you received any assurances or commitments from external partners (please specify)? We are particularly interested in seeing strong, shared commitment by high-level decision makers, practitioners, and researchers to make the project successful and to act upon important findings; where appropriate, we value executive level support and a willingness to rigorously test new solutions.

**Submission guidelines**

Proposals for all project categories should meet the following guidelines in no more than three pages total:

- Address each of the selection criteria in the relevant appendix for the appropriate project category;
- Be single- or double-spaced and use an 11-point font or larger;
- Specify the proposed recipient of the grant award, which LJAF generally expects to be a tax-exempt organization (e.g., public charity or governmental unit); and
- Specify the amount of funding required to conduct the proposed initiative. A budget may be submitted as an attachment to the proposal and will not count toward the three-page limit.

Proposals will be accepted on a rolling basis through Dec. 15, 2016. Please direct letters and questions to Evidence-BasedInnovationLOI@arnoldfoundation.org. If LJAF determines that your proposal meets the criteria outlined above, you may be asked to submit a full proposal.

**Additional information**

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Much of the spending on opioid treatment programs at the federal level takes the form of unrestricted block grants to the states, and amounts spent on specific treatments are not readily available. However, a comprehensive report from the Washington State Institute of Public Policy (2014) highlights MAT as among the only evidence-based treatment options for opioid abuse and SAMHSA’s most recent annual survey of substance abuse treatment services (2014, p. 2) states that MAT is administered in only 8 to 9 percent of opioid-treatment facilities nationwide.