

**Substance Abuse and Mental Health Services Administration
(SAMHSA)**

Policy and Procedure (P&P) Number: 04.01.01

P&P Title: Evaluation

Lead: Center for Behavioral Health Statistics and Quality (CBHSQ)

Approving Authority: Assistant Secretary for Mental Health and Substance Use

Effective Date: 05/26/2017

Revision Date: MM/DD/YYYY

- 1.0 Purpose:** This P&P provides guidance on implementing the recommendations of the 2016 SAMHSA Summer Evaluation Review as presented to the SAMHSA Executive Leadership Team (ELT) to guide SAMHSA in developing a long-term program evaluation plan based on the selection and use of the best methods for answering specific evaluation questions. These questions should be closely linked to program or research objectives and support both the independence and transparency of evaluation across the federal government. SAMHSA is actively working to develop a learning agenda to align its evaluation goals and activities with those of the Department of Health and Human Services (HHS).

- 2.0 Objectives:** All program evaluations, whether conducted by SAMHSA or an agent (i.e., contractor) of SAMHSA, will be conducted with a rigorous design and in an ethical manner while ensuring the safeguard, dignity, respect, rights, and privacy of all participants. Evaluations will comply with both the spirit and the letter of the relevant requirements that govern research involving human subjects. SAMHSA's updated evaluation policy is focused on achieving several key objectives:
 - 2.1** Consistently match the type of evaluation activity with program maturity, complexity, and research goals;
 - 2.2** Consistently ensure research goals are relevant, actionable, and defensible;
 - 2.3** Consistently match the degree of independence of the evaluation with the importance of the program, level of interest in the outcome from the key stakeholders (e.g., Congress, SAMHSA, center, grantee), and size, scope, and complexity of the evaluation activity;
 - 2.4** Consistently collect and share meaningful and critical findings within SAMHSA, with key stakeholders, and with the behavioral health and scientific communities;
 - 2.5** Consistently incorporate these practices and considerations into the contract planning process; and,

2.6 Consistently develop a “learning agenda” to identify priorities for future evaluation activities.

3.0 **Scope:** This P&P will cover all program evaluation activities. This includes all evaluation activities or evaluation contract mechanisms beginning in fiscal year (FY) 2018. Additionally, this P&P will cover any type of evaluation mechanism being executed in FY 2018 (e.g., evaluation contract, optional tasks, evaluation task orders, in-house evaluations, Inter-Agency Agreements), whether the mechanism originated during, or prior to, FY 2018. The principles, guidelines, and processes identified within this P&P are applicable to all SAMHSA staff, including federal civilian employees, Commissioned Corps Officers, interns, contractors, sub-contractors, and consultants.

4.0 **Definitions:**

4.1 **21st Century Cures Act:** legislation passed by Congress in December 2016 that requires the Assistant Secretary for Planning and Evaluation (ASPE) to develop an evaluation strategy that identifies priority programs to be evaluated and provide recommendations on improving programs and activities based on the evaluations conducted. Additionally, it requires ASPE to partner with SAMHSA and CBHSQ to “coordinate the Administration’s integrated data strategy [... and] coordinate evaluation efforts for the grant programs, contracts, and collaborative agreements of the Administration¹” in consultation with SAMHSA’s Chief Medical Officer (CMO).

4.2 **Contracting Officer’s Representative (COR):** the COR plays an integral role in the planning, monitoring, and closing out of contracts that support evaluation activities as described below. Selecting a COR with the appropriate skill set is important to ensure proper evaluation activities are conducted, research questions and evaluation design are matched to the grant/cohort/program’s level of maturity, and COR has the available time to manage the contractor throughout the lifecycle of the evaluation contract (from evaluation planning to completion).

4.3 **Cross Center Evaluation Review Board (CCERB):** the CCERB will review and provide oversight of significant evaluation activities (4.15 and 7.2.1.1.1) for SAMHSA, from contract planning to evaluation completion and at critical milestones, and is comprised of representatives from each of the centers, and Office of Tribal Affairs and Policy (OTAP) for cultural competency consultation, as necessary. Charter to be determined (TBD).

4.4 **Evaluation Activity:** any activity that is conducted to evaluate and/or assess a program, grantee, and/or cohorts to determine processes, outcomes, or costs of a program that are related to whether the program is having an impact, either

¹ ("21st Century Cures Act," 2016)
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intended or unintended, on the population or any sub population it is serving. Evaluation activities can take the form of formative (e.g., needs assessments, evaluability assessments), process, summative (e.g., outcome, impact, cost), or rapid cycle that are aimed to learn information relevant to the design, implementation, and conduct of the program, so that the information obtained can be used to directly improve the program and its activities, impact Funding Opportunity Announcements (FOAs), Training/Technical Assistance (T/TA), or make administrative changes. Evaluation activities can also overlap with performance measurement that occurs during the course of grant/program administration [e.g., Government Performance and Results Act (GPRA) measures, regular reporting requirements].

- 4.5 Evaluation Contract Planning Document:** a document specific to evaluations that is completed by relevant center program staff, as part of the contract planning process established by the Office of Financial Resources (OFR) within SAMSHA.
- 4.6 Evaluation Dashboard:** a list of current/ongoing, significant evaluation activities being conducted by SAMHSA and for which the general public should be made aware.
- 4.7 Evaluation Data Files:** a central repository that includes the original (raw) and cleaned evaluation data sets that were used to conduct the evaluation activity.
- 4.8 Evaluation Reports:** reports provided on an annual and final (i.e., at the end of the evaluation contract) basis to describe the progress of the grantee/cohort/program, evaluation methods, and results.
- 4.9 Formative Evaluations:** evaluations conducted prior to, or during, the early stages of program implementation to determine if the program can be implemented as intended and whether the program will have an effect on participants. They include evaluability assessments which are conducted to determine the maturity of the program and the level to which a more complete evaluation can be conducted^{2,3} and needs assessments which can be used to determine how to target resources and the degree of interest within the community⁴.
- 4.10 Independence of Evaluation:** the degree to which a program evaluation is conducted by a non-biased entity (e.g., contractor, individual) who does not have a conflict of interest with the grantee(s)/cohort(s)/program(s) for which services are being provided. As SAMHSA is a services agency, evaluation independence

² (Thurston, Graham, & Hatfield, 2003)

³ (Youtie, Bozeman, & Shapira, 1999)

⁴ (Windsor, Clark, Boyd, & Goodman, 2004)

spans a continuum from low to high. Low, medium, and high independence are defined below.

4.10.1 Low (or no) independence evaluation activities, are those that occur within a non-evaluation (i.e., T/TA) contract or only include the collection of performance measures (i.e., GPRA).

4.10.2 Medium (or moderate) independence evaluation activities may range from evaluation contracts that are overseen by the Center for Substance Abuse Prevention (CSAP), Center for Mental Health Services (CMHS), or Center for Substance Abuse Treatment (CSAT) CORs/Alternate CORs (ACOR) to evaluation activities where the COR/ACOR is housed outside of the program center (i.e., CBHSQ). These activities may also include evaluations performed within SAMHSA by Evaluation Desk Officers (EDOs) for small scale, rapid assessments.

4.10.3 High (or complete) independence evaluation activities may range from activities that are conducted or overseen by other Operating Divisions (OPDIVs) or Staff Divisions (STAFFDIVs), to evaluations conducted or overseen by the Government Accountability Office (GAO).

4.11 Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) Control Officer: the individual who reviews all OMB packages for all SAMHSA grants, contracts, and other activities when public data collection activities are proposed.

4.12 Process Evaluation: evaluations conducted to understand how the program works and whether the program was implemented with fidelity and reached the target population that it is intended to reach (coverage).^{5,6,7} Such evaluations are conducted for relatively young programs that have moved beyond the implementation phase and older programs that have changed substantially since implementation.⁸ Process evaluations should be conducted prior to summative evaluations, but in some instances they may be conducted together to better define the program model being evaluated or to identify variations in characteristics across sites or models that may be considered in the summative evaluation.

4.13 Rapid Cycle Evaluations: evaluations conducted on new/innovative programs to understand what is or is not working, what should be modified, and potential impacts of the program. They are generally based on administrative reviews

⁵ ibid

⁶ (Centers for Disease Control and Prevention, 2011)

⁷ (U.S. Government Accountability Office, 2009)

⁸ (W.K. Kellogg Foundation, 1998)

using experimental or quasi-experimental designs to determine the intended and unintended effects of the program (impact). The impacts of program changes are assessed as they are being made.⁹ These activities may be qualitative or quantitative in nature, depending on the timeframe and evaluation questions to be answered, and the results can be used to inform TA, FOAs, or program design.

- 4.14 Rigorously Designed Evaluations:** evaluations should be rigorously designed to the fullest extent possible and include “...inferences about cause and effect [that are] well founded (internal validity), [...] clarity about the populations, settings, or circumstances to which results can be generalized (external validity); and requires the use of measures that accurately capture the intended information (measurement reliability and validity).”¹⁰ The need for a rigorously designed evaluation will be balanced with the needs of the service organization, independence, cost, and significance, and take into account the need to conduct quasi-experimental, observational, or case study designs to include collection of additional data, targeting comparisons and gathering a diverse body of evidence where feasible. To the extent possible, rigorously designed evaluations should include one or more comparison groups.
- 4.15 Significant Evaluation Activity:** any evaluation activity identified by the center director that may provide compelling information and results that can be used to make data driven, evidence-based, and informed decisions about behavioral health programs and policy, and will be monitored by the CCERB.
- 4.16 SAMHSA Completed Evaluation Inventory:** a list of significant, and completed, evaluation activities.
- 4.17 Summative Evaluations:** evaluations that assess the impact and outcomes of the program and its effects on program participants, the broader health care delivery system, or social service delivery system (if applicable). Summative evaluations can be an evaluation of program outcomes, program impact, or program costs, or contain components of all three.¹¹ Outcome evaluations help determine if the program is conducting the right activities to bring about the changes described in the program’s mission statement and objectives.¹² Impact evaluations measure the effects of the program, both the intended and unintended consequences,¹³ and compare outcomes from the program to that which may have occurred in the absence of the program intervention.¹⁴ Cost evaluations can assess dollars spent

⁹ (Cody & Ascher, 2016)

¹⁰ (Administration for Children and Families, 2012)

¹¹ (The National Science Foundation, 2010)

¹² (W.K. Kellogg Foundation, 1998)

¹³ (Saskatchewan Ministry of Education, 2008)

¹⁴ (U.S. Government Accountability Office, 2009)

versus dollars saved (cost-benefit), or assess the cost of the program relative to the cost of each improvement or outcome generated (cost-effectiveness).¹⁵

Summative evaluations should occur after a process evaluation, but in some instances, process and summative evaluations may be conducted together to better define the program model being evaluated or to identify variations in characteristics across sites or models that may be considered.

4.18 Sustainability: a concept that describes how programs become routinized for a provider, community or state in terms of infrastructure, practice, funding sources, or cultural changes that ultimately support program longevity. It assesses whether full-time staff and program budgets and funding are maintained so the activities can continue or become a natural part of the organization in which it operates.^{16,17,18}

5.0 Background: Program evaluation activities are defined as the systematic application of social research and evaluation procedures to assess the conceptualization, design, implementation, effectiveness, and efficiency of a program.¹⁹ The GAO describes evaluation as “individual systematic studies conducted periodically or on an ad hoc basis [using research methods to collect and analyze data] to assess how well a program is working” and why.^{20,21} In addition, HHS, OMB, and Congress continue to place great emphasis on evidence-based decision making, requiring a thoughtful, transparent, and systematic approach to how the federal government generates information and uses that information to improve the effectiveness of its programs.

5.1 In recognition of the need to formalize a systematic approach to planning, managing, and overseeing evaluation activities involving SAMHSA programs, CBHSQ, in collaboration with CMHS, CSAP, and CSAT, undertook a review of ongoing and completed SAMHSA evaluations in the summer of 2016. The final report²² of this summer exercise identified the need across the SAMHSA portfolio to:

5.1.1 Consistently match the type of evaluation activity with program maturity, complexity, and research goals;

5.1.2 Consistently determine the degree of independence of evaluation activities for different types of programs;

¹⁵ (Saskatchewan Ministry of Education, 2008)

¹⁶ (Pluye, Potvin, Denis, & Pelletier, 2004)

¹⁷ (Shediac-Rizkallah & Bone, 1998)

¹⁸ (Scheirer & Dearing, 2011)

¹⁹ (Rossi, Lipsey, & Freeman, 1993)

²⁰ (U.S. Government Accountability Office, 2011)

²¹ (U.S. Government Accountability Office, 2012)

²² (Substance Abuse and Mental Health Services Administration, 2016)

- 5.1.3 Consistently incorporate these practices and considerations into the contract planning process;
 - 5.1.4 Consistently collect and disseminate meaningful and critical findings to SAMHSA’s colleagues and to the behavioral health and scientific fields; and,
 - 5.1.5 Develop a “learning agenda” to identify priorities for future evaluation activities.
- 5.2 The findings, from the summer evaluation exercise²³, were presented to ELT who agreed to work with CBHSQ on the following action steps:
- 5.2.1 Update the 2012 SAMHSA Evaluation Policy²⁴ to address the needs identified in the final report, including the role of the SAMHSA Evaluation Team (SET), in planning and monitoring significant evaluation activities;
 - 5.2.2 Enhance the SAMHSA contract planning process to allow for review and approval of critical evaluation components, including the development of any necessary boilerplate language;
 - 5.2.3 Identify or create a central location on the SAMHSA website for evaluation reports, summary of findings, and data collected for these deliverables;
 - 5.2.4 Create a dashboard of current/ongoing significant evaluations and an inventory of completed significant evaluations; and,
 - 5.2.5 Develop a SAMHSA learning agenda.

6.0 Responsibilities:

- 6.1 **Primary Author:** CBHSQ, Division of Evaluation, Analysis and Quality (DEAQ)
- 6.2 **CBHSQ P&P Coordinator:** Chief, Quality, Evaluation, Performance Branch (QEPB)
- 6.3 **CBHSQ P&P Manager:** Director, DEAQ
- 6.4 **Responsible Party:** Director, CBHSQ

²³ ibid

²⁴ (Substance Abuse and Mental Health Services Administration , 2012)
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7.0 Procedures:

7.1 Development of Evaluation Strategy: TBD

7.2 Evaluation Planning and Oversight: CBHSQ shall coordinate with the Office of Financial Resources (OFR) and Office of the Chief Medical Officer (OCMO) to review evaluation activities undertaken through the Contract Planning Process (7.2.1) and the Contract Management Process (7.2.2), and to review other evaluation activities undertaken through other planning (7.2.3) and other management (7.2.4) processes in order to determine whether such evaluation activities are consistent with the maturity of the program, research questions, and degree of independence necessary to conduct a rigorous evaluation to the fullest extent possible as outlined in the Purpose (1.0) and Objectives (2.0), combined with Executive and HHS directives, and the 21st Century Cures Act. In addition, CBHSQ, through collaboration with the Center’s program representatives and OFR, will also assist with the FOA development process and development of T/TA activities. Where appropriate, detail will be incorporated into FOAs to ensure the necessary data collection through measure definition and support of the required grantee infrastructure and other evaluation related activities.

7.2.1 Contract Planning Process: At the start of the contract planning process, OFR will share a list of proposed new contracts with CBHSQ to identify which ones will require CCERB review. For those contracts, a planning document specifically for evaluation will be utilized (Evaluation Contract Planning Document [7.2.1.1]). Five additional fields have been added to the standard contract planning document template. These include significant evaluation activities, degree of independence, evaluation type, COR designation, and research questions.

These additional data fields are further described in the Evaluation Contract Planning Document Section (7.2.1.1.), as outlined below, and in the updated Planning Document for NEW/RECOMPETE Evaluation Contracts (hereafter referred to as “Evaluation Contract Planning Document” [Attachment 1]) and are being added to ensure a consistent approach across the centers while being responsive to the evaluation and review process. Additionally, this increased management reflects Executive and HHS guidance and the 21st Century Cures Act on improving evaluation activities and assessing mental health and substance use disorder treatment and prevention programs. Once the document is completed, it will be posted to SharePoint and routed for comment/clearance through the OFR contract planning process.

7.2.1.1 Evaluation Contract Planning Document: An updated contract planning document that adds five fields to the existing contract planning document.

7.2.1.1.1 Significant Evaluation Activities: A significant evaluation activity (4.15) is an activity identified by the Center Director or his/her designee (hereafter referred to as “Center Director”) that will provide compelling information and results that can be used to make data-driven, evidence-based, and informed decisions about behavioral health programs and policy. Significant evaluations will be monitored by the CCERB (4.3) and posted to the SAMHSA website (<http://www.samhsa.gov>; 7.2.8).

Identifying significant evaluation activities is important because it provides credible evidence of findings relevant for the behavioral health planning and policy work conducted by ASPE, contributes to the behavioral health and scientific fields, and impacts program administration and policy as further defined in this P&P.

As part of the contract planning process, the Center Director will determine whether each activity is considered a significant evaluation and provide a brief rationale for its designation in the Evaluation Contract Planning Document (Attachment 1).

The Center Director should consider the following factors to determine whether each evaluation activity should be considered significant:

- 7.2.1.1.1.1** Whether the evaluation is mandated by Congress;
- 7.2.1.1.1.2** Whether there are high priority needs in states and communities;
- 7.2.1.1.1.3** Whether the evaluation is for a new or congressionally-mandated program;
- 7.2.1.1.1.4** The extent to which the program is linked to key initiatives;

- 7.2.1.1.1.5 The level of funding per year (suggested \$500,000 threshold) and/or over the life of the contract (suggested \$2,000,000 threshold per FOA);
- 7.2.1.1.1.6 Level of interest from internal and/or external stakeholders; and,
- 7.2.1.1.1.7 Potential to inform practice, policy or budgetary decision-making.

7.2.1.1.2 Degree of Independence: An evaluation's degree of independence can reflect a continuum from high (or complete) independence, medium (or moderate) independence, to low (or no) independence. Determining the appropriate degree of independence is important to ensure that real or potential conflicts of interest do not exist between the entities conducting the evaluation and the grant/cohort/program being evaluated. An increased level of independence can also help prevent bias in the conduct and outcome of the evaluation and its findings.

As part of the contract planning process, the Center Director will determine the degree of evaluation independence (high, medium, or low) and provide a brief rationale for their decision on the Evaluation Contract Planning Document (Attachment 1). Definitions for each level of independence (low, medium, high) are presented in Section 4.10.

The Center Director should consider the following factors to determine independence:

- 7.2.1.1.2.1 The level of maturity of the grant/cohort/program;
- 7.2.1.1.2.2 Whether the evaluation activity is funded by another OPDIV or STAFFDIV;
- 7.2.1.1.2.3 Whether the evaluation is congressionally-mandated;

- 7.2.1.1.2.4 The extent to which the program is controversial or a matter of elevated public interest;
- 7.2.1.1.2.5 The importance and relevance of the findings to the scientific and behavioral health fields and/or the SAMHSA or HHS mission;
- 7.2.1.1.2.6 The potential impact of the results on evidence-based practices; and,
- 7.2.1.1.2.7 The potential impact of the results on substance use or mental health policies.

7.2.1.1.3 Evaluation Type: Evaluation activities include rapid cycle (4.13), formative (4.9), process (4.12), and summative evaluations (4.17) which span the continuum of grant/cohort/program development; planning, implementation, and outcomes (or impact).

Selecting the appropriate type of evaluation is important to ensure that the activities are well-matched to the maturity of the grant/cohort/program; research questions are addressed; and the evaluation complements or builds on existing knowledge and is likely to provide results that are relevant, actionable, and high-quality.

As part of the contract planning process, the Center Director will determine the type(s) of evaluation being planned (formative, process, summative, rapid cycle) and provide a brief rationale on the Evaluation Contract Planning Document (Attachment 1).

The Center Director should consider the following factors to determine the type of evaluation to be conducted:

- 7.2.1.1.3.1 Capacity to answer the proposed research question;

- 7.2.1.1.3.2 Capacity to build on existing data and findings from prior grant/cohort/program evaluations;
- 7.2.1.1.3.3 Adequate match with the maturity of different grants/cohorts/programs;
- 7.2.1.1.3.4 Ability to minimize repetition of prior evaluations;
- 7.2.1.1.3.5 Need to evaluate changes to a program design;
- 7.2.1.1.3.6 Sufficient funding to adequately finance the research design and generate robust results;
- 7.2.1.1.3.7 Sufficient data available to answer the evaluation questions; and,
- 7.2.1.1.3.8 Need to secure OMB clearance for new/modified data-collection instruments.

7.2.1.1.4 COR Designation: The COR plays an integral role in the planning, monitoring, and completion of contracts that support evaluation activities as described further below. Selecting a COR with the appropriate skillset (and grant/cohort/program knowledge, to the extent possible) is important to ensure proper evaluation activities are conducted and the research questions and evaluation design are matched to the grant/cohort/program’s level of maturity.

The following factors to should be considered in selecting the appropriate COR /ACOR for the evaluation contract:

- 7.2.1.1.4.1 Relevant evaluation (and grant/ cohort/ program) experience and level of complexity for the contract;
- 7.2.1.1.4.2 Prior performance on other evaluation contracts;

7.2.1.1.4.3 Experience with, or expertise related to, the type of evaluation(s) to be conducted.

7.2.1.1.5 **Research Questions:** The identification of key research questions is an important step in the evaluation planning process and should be done early in collaboration with grant/cohort/program staff to ensure that the design of the proposed evaluation is well-matched to the needs and resources of the grantee/cohort/program.

As part of the contract planning process, the Center Director will determine the proposed research questions and provide a brief rationale on the Evaluation Contract Planning Document (Attachment 1). An example of a completed (and approved) contract planning document with minor modifications for generalizability is provided in Attachment 2.

The Center Director should consider the following factors to determine the appropriate research questions:

7.2.1.1.5.1 Adequate match with the current needs of the grant/cohort/program;

7.2.1.1.5.2 Adequate match with the evaluation design and planned data collection activities;

7.2.1.1.5.3 Relevance to the cohort/grant/program's maturity;

7.2.1.1.5.4 Builds on findings from previous evaluation activities, and/or existing literature; and,

7.2.1.1.5.5 Avoidance of repetition of prior evaluation(s) for the same grant/cohort/program.

7.2.1.2 **Requests for Contracts (RFC)/Request for Task Order Proposals (RFTOP) Package:** During the Contract Planning Process, a review of the final RFC/RFTOP package will be

conducted by the CCERB to ensure compliance with the approved evaluation planning document and to ensure that the package includes standard language on the collection of evaluation final reports and evaluation data files. Once the evaluation is completed (7.2.2.3), SAMHSA will ensure that all relevant evaluation files are received. These files include the evaluation final report which will be posted publicly on the SAMHSA website (<http://www.samhsa.gov>; 7.2.8), and the evaluation data files which will be posted internally to the SAMHSA Intranet (<https://newintranet.samhsa.gov>), with eventual public release, as applicable and feasible, with the level of resources allocated to evaluation activities (7.2.9).

7.2.1.2.1 RFC/RFTOP Standard Language: The RFC/RFTOP package will include standard language that indicates the format of the evaluation final reports. The language will provide a general outline and structure for evaluation final reports and instruct contractors that either the full report, or the executive summary, will be posted on the publicly available SAMHSA website (<http://www.samhsa.gov>), at SAMHSA's discretion. The standard language for evaluation reports (Attachment 3) is designed to increase transparency of the evaluations being conducted by SAMHSA, ensure standardization of evaluation final reports, and facilitate tracking and posting of completed evaluation reports (7.2.8).

Standard language for the collection of all relevant evaluation data files (Attachment 4) is included to ensure ownership and collection of data by SAMHSA (7.2.9) and to facilitate release of such data for internal and external research purposes, as practicable. Collection and release of the evaluation data is important because it comports to the Evidence Based Commission Act of 2016²⁵, OMB A-011 Guidance,²⁶ and the HHS Evidence and Evaluation Policy Council.

²⁵ ("Evidence-Based Policymaking Commission Act of 2016," 2016)

²⁶ (Office of Management and Budget, 2016)

7.2.2 Contract Management Process: After contract award, CBHSQ/QEPB and the CCERB will continue to work with the Center's grant/cohort/program representatives and the evaluation COR/ACORs throughout the contract management process to include key milestone reviews of significant evaluation activities (7.2.1.1.1) and evaluation completion (7.2.2.3). Active contract management is necessary to ensure SAMHSA receives all goods and services as contracted, the evaluation is relevant to the grant/cohort/program, and SAMHSA is able to use findings from the evaluation to improve mental health and substance use prevention and treatment services, improve T/TA or administrative functions of the program, and identify programs that are proven to be effective.

7.2.2.1 Milestone Review: A structured review of significant evaluation activities by the CCERB (7.2.1.1.1) will occur at key contract milestones. The additional oversight will ensure relevance of the evaluation design, identification of possible issues during annual reviews that can potentially be addressed prior to final review, and participation in key briefings to better understand the grant/cohort/program, the evaluation design, and ensure SAMHSA receives all contracted goods and services upon evaluation completion (7.2.2.3). The key milestones include:

7.2.2.1.1 Draft version of the evaluation design including finalized research questions as well as data collection and analysis plans;

7.2.2.1.2 Draft version of the annual evaluation report;

7.2.2.1.3 Draft version of the evaluation final report;

7.2.2.1.4 Significant briefings as determined by the contract; and,

7.2.2.1.5 Evaluation completion (7.2.2.3) to determine if all evaluation materials (i.e., evaluation final report, evaluation data files) have been received.

7.2.2.2 OMB Paperwork Reduction Act (PRA) Clearance Process: The OMB PRA Clearance Process begins with the creation of an OMB Clearance Package that is drafted by center or contract staff and submitted electronically to CBHSQ's OMB PRA Control Officer (4.11) for review. After the Control Officer

determines all relevant information is provided and signs off on the materials, the package will be sent to CBHSQ/QEPB for review. OMB clearance packages that include evaluation activities will undergo greater review within CBHSQ/QEPB. This increased review is necessary to ensure that the research questions are relevant to the evaluation design and maturity of the grantee/cohort/program, and to ensure that data collection will answer the research questions and not unduly burden the respondents or the program staff collecting the data. After the QEPB clears the materials, the OMB Control Officer will return the package to the center Project Officer for clearance through their center. Once the originating center director approves the materials, the memo and Federal Register Notice (FRN) will be uploaded into SWIFT by the center. After the materials are approved in SWIFT by CBHSQ's Center Director, they will be sent to the Executive Correspondence Branch in the Division of Policy Coordination, Office of Policy, Planning and Innovation (OPPI), SAMHSA, for approval by the Assistant Secretary for Mental Health and Substance Use or Deputy Assistant Secretary for Mental Health and Substance Use.

7.2.2.3 Evaluation Completion: The completion of the evaluation, and submission of the evaluation final report and evaluation data files, are the final steps in the process and are integral to ensuring all goods and services have been delivered by the contractor to SAMHSA. Additional oversight of this process by CCERB, as relevant, will ensure that all reports and data sets (qualitative and quantitative) have been received by the COR. Additionally, it will ensure receipt of a 508 compliant evaluation final report for posting to the publicly available SAMHSA website (<http://www.samhsa.gov>; 7.2.8), and receipt of all evaluation data files (7.2.9) for posting, as relevant. The oversight will also ensure the collaboration of the COR, EDO, Office of Communications (OC), OCMO, CCERB (as applicable), and the lead center director in completing the Evaluation Final Report Clearance Form (Attachment 5). Completion of the Evaluation Final Report Clearance Form will ensure that evaluation final reports (7.2.8) have been reviewed by all members as relevant, that a consensus has been reached on whether the full report or only the executive summary will be released, and that OC has published the report on the SAMHSA website (<http://www.samhsa.gov>).

7.2.3 Other Planning Process:

7.2.3.1 Inter-Agency Agreements: TBD

7.2.3.2 In-House: TBD

7.2.3.3 Other: TBD

7.2.4 Other Management Process:

7.2.4.1 Inter-Agency Agreements: TBD

7.2.4.2 In-House: TBD

7.2.4.3 Other: TBD

7.2.5 Establish and Maintain Evaluation Dashboard: Establishing and maintaining an evaluation dashboard will facilitate tracking the progress and other relevant information of current/ongoing significant evaluations through the contract lifecycle process from evaluation contract planning (7.2.1) and management (7.2.2) to evaluation completion (7.2.2.3) and at key milestones (7.2.2.1). Tracking of significant evaluations will better facilitate evaluation reports being made available to SAMHSA, stakeholders (e.g., Congress, grantees), and the scientific community while ensuring transparency. Transparency of ongoing and completed significant evaluations is in alignment with HHS and Executive guidelines, and the 21st Century Cures Act, which mandates that SAMHSA work with ASPE and the OCMO in identifying best practices to improve mental health and substance use prevention and treatment programs.

CBHSQ will work with CMHS, CSAT, and CSAP Center Directors to identify a list of current/ongoing significant evaluation contracts that include significant evaluation activities which they would like included in the SAMHSA Evaluation Dashboard.

CBHSQ will work with the Office of Management, Technology, and Operations (OMTO), and other relevant offices, to identify a central location for the dashboard to initially be posted internally on the SAMHSA intranet (<https://newintranet.samhsa.gov>), and determine the process for making components of the dashboard publicly available on the SAMHSA website (<http://www.samhsa.gov>).

CBHSQ will update the dashboard annually with input from CMHS, CSAT, and CSAP Center Directors and grant/cohort/program staff, and CMO, as relevant.

- 7.2.6 Establish and Maintain SAMHSA Completed Evaluation Inventory:** Establishing and maintaining a SAMHSA Completed Evaluation Inventory, to include Evaluation Final Reports (7.2.8), is important to track significant evaluations that have been completed by the agency and to ensure that the final reports are made available to SAMHSA, stakeholders (e.g., Congress, grantees), scientific community, and public, in an easily accessed central location. The additional oversight and publication of the SAMSHA Completed Evaluation Inventory and Evaluation Final Reports will ensure transparency of significant SAMHSA evaluations and is in alignment with HHS and Executive guidelines and the 21st Century Cures Act.

CBHSQ will work with CMHS, CSAT, and CSAP Center Directors and grant/cohort/program staff, as appropriate, to identify an initial list of evaluations that have been completed between FY 2011 and FY 2017, and to obtain their evaluation final reports, as available. CBHSQ will also work with OMTO to identify a central location on the SAMHSA intranet (<https://newintranet.samhsa.gov>) to publish the SAMHSA Completed Evaluation Inventory (and final reports) for FY 2011- FY 2017.

Additionally, CBHSQ will also work with OMTO to identify a location on the publicly available website (<http://www.samhsa.gov>) for publishing a list of significant and completed evaluations (and their associated Evaluation Final Reports [7.2.8] that have been reviewed and cleared according to the evaluation completion process [7.2.2.3]). Publishing these reports according to the new process described in this P&P will begin as soon as practicable following adoption of the P&P. The list will be updated annually by reviewing the information contained in the Evaluation Dashboard (7.2.5) and will include additional information provided by grant/cohort/program staff and their respective center director's.

- 7.2.7 Establish and Maintain ASPE Performance Improvement Reports (PIRs) Submitted by SAMHSA:** The 21st Century Cures Act mandates that SAMHSA work with ASPE to assess SAMHSA's mental health and substance use disorder treatment and prevention programs. Historically, ASPE has requested that SAMHSA annually provide completed PIRs that describe completed evaluation activities of its substance use and mental health programs.

CBHSQ will work with CMHS, CSAT, and CSAP evaluation staff annually to obtain a list of completed evaluation activities and completed PIRs for submission to the Assistant Secretary for Mental Health and Substance Use or Deputy Assistant Secretary for Mental Health and Substance Use for review and approval. CBHSQ will maintain the list and summaries that are approved and submitted to ASPE.

7.2.8 Establish and Maintain Evaluation Final Report Repository:

Establishing and maintaining Evaluation Final Reports in a single location is important to ensure results from significant evaluation studies are made available and easily accessible to SAMHSA (to include the OCMO), stakeholders (e.g., Congress, grantees), scientific community, and the public. Publishing such reports ensures transparency of significant evaluations conducted by SAMHSA and that the evaluation results will help the behavioral health and scientific communities, and stakeholders, better understand which mental health and substance use disorder treatment and prevention programs are effective, and for which populations.

CBHSQ will work with OMTD, and other offices as relevant, to initially identify a central location on the SAMHSA Intranet (<https://newintranet.samhsa.gov>) for all SAMHSA evaluation final reports during FY 11- FY 17.

CBHSQ will also ensure that a repository for significant evaluation final reports is provided on the publicly available SAMHSA website (<http://www.samhsa.gov>) for reports that are reviewed and cleared according to the evaluation completion process (7.2.2.3), following adoption of this Evaluation P&P.

The additional oversight and sharing of the evaluation final reports will ensure coordination, transparency, and a standard approach to the release of findings, whether they are positive, neutral, or negative, to SAMHSA or the grant/cohort/program being evaluated.

7.2.9 Establish and Maintain Evaluation Data files: Establishing a central location for evaluation data files will ensure the agency obtains all analytic evaluation data files (quantitative and qualitative), data dictionaries, code books, and annotated syntax from the contractor prior to contract completion and are not lost to the agency. The central location for these data sets will ensure easy access to relevant files if additional research is conducted by SAMHSA employees or if research requests are made by outside entities. It also facilitates making the data publicly available while adhering to confidentiality and other relevant requirements.

CBHSQ and the CCERB will provide additional oversight to ensure the evaluation data files are obtained at evaluation completion (7.2.2.3).

CBHSQ will work with OMTD, and other offices as relevant, to identify a central location on the SAMHSA Intranet and explore the feasibility of making the data files available to researchers, or the public, as relevant and feasible given the level of resources available. The process for reviewing and determining release of evaluation data files to researchers via restricted access (i.e., Substance Abuse and Mental Health Data Archive) can be found in the relevant CBHSQ Standard Operating Procedures.

7.2.10 Establish and Maintain Agency Learning Agenda: TBD

8.0 Special Requirements:

8.1 P&P Renewal Frequency: This P&P should be reviewed in its entirety every two years from the effective date. It should also be reviewed annually to ensure hyperlinks are functioning and appropriate.

8.2 The P&P Manager should have a working knowledge of SharePoint 2013 in order to effectively post and archive P&P documents on the P&P Library and its related work area.

9.0 Revision History:

Revision Date	Section	Impact	Revision
N/A			

10.0 References and Attachments:

References:

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Attachments:

1. Planning Document for NEW/RECOMPETE Evaluation Contracts
2. Evaluation Final Report – Proposed Standard Language

3. Evaluation Data Files - Proposed Standard Language
4. Evaluation Final Report Clearance Form

Attachment 1

Planning Document for NEW/RECOMPETE Evaluation Contracts

Lead Center/Office:

Contract Title:

Only complete this section for RECOMPETE contracts:

Current Contract #:

Current Contract End Date:

Incumbent Contractor:

1. Competition Type:

If IDIQ, which domain:

(e.g., Full/Open, Small Business, Indefinite Delivery, Indefinite Quality [IDIQ])

- Domain I. Feasibility, Pilot, and Evaluation Projects
- Domain II. Statistical Projects
- Domain III. Policy Analysis and Program Related Projects
- Domain IV. Communications Projects
- Domain V. Technical Assistance (TA) and Training Projects
- Domain VI. Planning, Implementation, and Report Support Projects

Please select the type of evaluation being planned and provide rationale. (Select all that apply).

Formative

Process

Summative

Rapid-Cycle

Please provide rationale:

2. Please select the level of independence for the evaluation activities and provide rationale. (Select one).

Low Medium High

Please provide rationale:

3. For evaluation contracts, please identify whether this is a Significant Evaluation Activity and provide rationale.

Yes No

Please provide rationale:

Proposed Award Date:

Length of Contract:

Funding for Core Tasks:

	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	Total
Subtotal						
Total Contract Amount						

4. Rationale for Determining Total Contract Amount:

Based on previous contract doing same work
 Based on a contract doing similar work
 New contract; used market research to determine cost
 Other (Please specify below)

5. Funding Mechanisms: (For contracts that are funded from multiple budget lines/standard lines of accounting [SLoAs])

Purpose/Summary of the Contract: *(No more than one paragraph)*

6. Please list the key research questions:

Major Tasks (Core Work): *(Add/delete rows as needed)*

Major Tasks (Core Work)	Funding %	Conference/ Exception Approval Required? Yes or No

Key Deliverables: *(i.e., what products and/or services the contract is purchasing)*

Optional Task: *(Add/delete rows as needed. NOTE that non-SAMHSA funds can only be for optional tasks.)*

Brief Description of Optional Task	Center/Office or Federal Partner has FY 2017 funding? Yes or No	If yes, Amount and Source of FY 2017 funds	Conference/Exception Approval Required? Yes or No

7. Justification and/or Special Considerations: *(Discuss any special issues or considerations for this procurement, e.g., conference or IT review/approval requirements, including dates affecting timing of award; need to wait for resolution by Congress on parameters; questions or issues raised by OMB or ASFR; policy or program changes from current practice; or political sensitivities.)*

8. Name of Contracting Officer Representative (COR):

Name of Center/Office and Division/Branch:

Phone number for COR:

Level of COR Certification:

Please explain reasoning for choosing said COR:

Name of Alternate COR (ACOR):

Name of Center/Office and Division/Branch:

Phone number for ACOR:

Level of ACOR Certification:

Please explain reasoning for choosing said ACOR(s):

This planning document has been reviewed and cleared by:

Name	Signature	Date

9. Follow-up Notes (if needed) TO BE COMPLETED BY OPPI/OFR:

Attachment 2

EXAMPLE

FY 2018 Planning Document for NEW/RECOMPETE Contracts²⁷

EXAMPLE

Lead Center/Office: CBHSQ

Contract Title: State Targeted Response to the Opioid Crisis (Opioid STR) Evaluation

Only complete this section for RECOMPETE contracts:

Current Contract #:

Current Contract End Date:

Incumbent Contractor:

1. Competition Type: IDIQ **If IDIQ, which domain:** Evaluation
(e.g., Full/Open, Small Business, IDIQ, etc.)

a. **Contract Type:** Evaluation

(e.g., logistics, TA, MDMS, evaluation, data, etc. If there is more than one appropriate contract type, please indicate the type that represents the largest part of the contract.)

2. For evaluation contracts, please select the type of evaluation being planned and provide rationale. (Select all that apply).

Formative **Process** **Summative** **Rapid Cycle**

²⁷ Modified State Targeted Response to the Opioid Crisis (Opioid STR) planning document for generalization purposes.
P&P 04.01.01 – CBHSQ: Evaluation

Please describe:

Given the complexity and variety of findings (e.g., prevention, treatment, recovery, community-level, and client-level) necessary for a successful evaluation of this critical response to the nation’s opioid crisis, CBHSQ proposes a multi-level, multicomponent evaluation to be conducted, at a minimum, for the two years of grant funding available to the states. The evaluation plan includes four inter-related components: a rapid cycle evaluation, a formative evaluation, a process evaluation, and a summative evaluation.

The rapid cycle component will be implemented immediately upon grantee award with a subset of the grantees to ensure that initial grantee data are not lost to us as programs are initiated. The large scale, national evaluation will include formative, process, and summative components. To continue to inform the agency’s opioid work and this activity, CBHSQ will provide support from their health economics and community behavioral health assessment teams to conduct policy and financing analyses related to naloxone, prescription drug monitoring programs (PDMPs), and Good Samaritan laws, among other topics, as well as community-level analyses of key topics of importance.

The rapid cycle component of the evaluation (generally conducted in six months to one year) will focus on new or innovative treatment, prevention, or recovery efforts that have been implemented by the grantees, starting in April 2017. To complete this component of the evaluation, a select number of grantees (approximately six states) will be chosen to describe their innovative programs in greater detail and to better understand what is working and for whom (i.e., which subpopulation[s]), so that programs can receive more immediate feedback about their progress, barriers, strategies to address those barriers, and performance, and to help determine potential impacts of the program.

The formative component of this evaluation, which includes needs assessment and evaluability assessment, will be conducted with all state and territorial grantees, with subgroups identified (to the extent possible) for comparison purposes, to determine how opioid treatment, prevention, and recovery programs were implemented, and the policies and structures in place to facilitate implementation of these programs. The information will be helpful to better understand what considerations were used to implement primary and secondary prevention, treatment, and recovery programs, and to better understand the sustainability of such programs. As directed by Congress, this portion of the evaluation will provide us with aggregate community-level data.

The process evaluation component will also be conducted with all grantees. The process evaluation will describe the prevention, treatment, and recovery activities and services that are implemented within each state (or jurisdiction). The evaluation will help us to better understand how prevention, treatment, and recovery programs were implemented, which evidence-based practices (EBPs) were chosen, and for which populations, will provide information on challenges to and facilitators of implementation while providing insight on the extent to which the programs can be evaluated, and will provide information about grantee’s capacity to provide and use data relevant to the Opioid STR. As directed by Congress, this portion of the evaluation will provide

us with community-level data. The process evaluation will also highlight whether strategies were implemented successfully, whether EBPs were implemented with fidelity, and whether the program reached the intended targeted population.

Finally, the summative evaluation component will be conducted with 10 states representing each HHS region and will facilitate gathering client-level data to demonstrate a more direct impact of grantees' funding. Funding constraints require us to focus on a limited amount of client-level data. By focusing on one state per HHS region, valuable data will be obtained for that particular region. Should additional funding be made available, CBHSQ can replicate this model for other states and providers. Within each state, one or more local demonstrations of the state's funded effort will be selected and will participate in a summative evaluation to determine the immediate and short term impact of the selected sites' funded activities related to the aims of the grant program: increased access to treatment for opioid use disorder; reduction of unmet treatment needs; and, reduction of opioid overdose related deaths. This may include attention to, among other areas of focus, medication assisted treatment (MAT) access, naloxone access and saturation, and community readiness for engagement around addressing the opioid epidemic.

3. For evaluation contracts, please select the level of independence for the evaluation activities and provide rationale. (Select one).

Low Medium High

Please describe: Determining the appropriate degree of independence for an evaluation is important to ensure real or potential conflicts of interest do not exist between the entities conducting or overseeing the evaluation and the entity being evaluated. Increased levels of independence can also help prevent bias in the conduct and outcome of the evaluation and its findings. The level of independence for this evaluation will be Medium. The proposed COR for this contract, Laura Jacobus-Kantor (CBHSQ), is housed outside of the program centers overseeing the grant programs. The proposed rapid cycle evaluation component will be conducted by CBSHQ staff, in collaboration with contractors, and in consultation with colleagues from CSAP and CSAT. Given the visibility and importance of this initiative to SAMHSA and HHS, this level of independence is appropriate. CBHSQ staff is currently engaged in collaborations with ASPE colleagues on a variety of evaluation activities, including the Assisted Outpatient Treatment Program and the Certified Community Behavioral Health Clinics (CCHBC)/223. In addition, CBHSQ has worked closely with CSAP in their naloxone activities and the evaluation of naloxone currently underway by the Centers for Disease Control and Prevention (CDC). For the purposes of this evaluation, CBHSQ will establish regular check-ins with ASPE and CDC to ensure that federal partners are kept abreast of the activities and are able to provide input into the evaluation activities as they unfold.

4. For evaluation contracts, please identify whether this is a Significant Evaluation Activity and provide rationale.

Yes No **Please describe:**

The planned evaluation will provide SAMHSA and HHS with important information regarding the Opioid STR grants.

The amount of funding allocated to the Opioid STR program (up to \$1,000,000,000 over two years) and the clinical importance and the high visibility of this project to SAMHSA, HHS, Congress, and the field, necessitates identifying this as a Significant Evaluation Activity that will be closely monitored at key milestones.

Proposed Award Date: April 2017

Length of Contract: Two years

Funding for Core Tasks:

	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	Total
Evaluation						
Subtotal						
Total Contract Amount						

5. Rationale for Determining Total Contract Amount:

Based on previous contract doing same work
 Based on a contract doing similar work
 New Contract; used market research to determine cost
 Other (Please specify below)

6. Funding Principles: *(For contracts that are funded from multiple budget lines/SLoAs)*

N/A

Purpose/Summary of the Contract: *(No more than one paragraph)*

The purpose of the contract is to conduct an evaluation of the state Opioid STR grant program. The evaluation will be designed to utilize several types of evaluation to adequately capture the complexity of states' and communities' opioid response within a two year timeframe. CBHSQ will engage in rapid-cycle, formative, process, and summative evaluation, in order to adequately assess the impact of this new funding to address the opioid crisis. The evaluation will utilize

rapid cycle methods that will facilitate collection of information on how grantees are implementing services, to identify potential technical assistance (TA) needs, and to summarize information that may guide additional evaluation questions. Because this is a new grant program, which is not prescriptive in nature but quite broad in the activities that states (and local communities) may adopt, and given the anticipated length of the grant awards (only 24 months), the planned evaluation will also rely heavily on formative and process evaluation methods. Finally, this evaluation will collect data relevant to outcomes in a small number of key, information rich sites. These data will provide information on outcomes such as treatment utilization, substance use, and opioid-related overdose/deaths.

7. For evaluation contracts, please list the key research questions:

Rapid cycle evaluation (to begin with grant awards in April 2017. Activities will focus on approximately six states).

The rapid cycle evaluation will focus on questions such as:

1. How is each state implementing prevention, treatment, and/or recovery efforts to address the opioid crisis?
2. What have been the barriers and facilitators (e.g., funding, partnerships, community engagement, and key program or policy champions) to conducting primary and secondary prevention, treatment, and/or recovery efforts to address the opioid crisis?
3. What structures, processes, and policies are currently in place at the state or community level to respond to the opioid crisis (e.g., Good Samaritan laws, naloxone access laws [i.e., standing orders/collaborative practice agreements] and/or distribution sites, access to PDMP for surveillance, planning, and clinical purposes, and integrated community care models)?
4. What are the state's/community's technical assistance needs around opioid prevention, treatment, and recovery services?
5. What EBPs are selected, how were they chosen, and why? What is the readiness to implement EBPs?

Formative evaluation (Activities will focus on up to 50 states and will include subgroups identified for comparison purposes to the extent possible.)

The formative evaluation component will focus on questions such as:

1. To what extent has the needs assessment provided by states as a requirement in the funding opportunity announcement (FOA) provided data and information relevant to key indicators as noted in the FOA?
2. How do states differ in their capacity to respond to the opioid crisis (e.g., access to PDMP information, behavioral health data collection/reporting occurring at the community level, geographic and cultural diversity, identifying and responding to population[s]) affected, addressing health disparities issues, leveraging funds from other sources (local, state, or national) and political will)?
3. What structures and/or processes are in place at the state or community level to respond to the opioid crisis (e.g., Good Samaritan laws, naloxone access laws [i.e., standing orders/collaborative practice agreements] and/or distribution sites, syringe services programs, access to PDMP for surveillance, planning, and clinical purposes, integrated community care models)?

Process evaluation (Activities will focus on all states/territories)

The process evaluation component will focus on questions such as:

1. How is each state implementing primary and secondary prevention, treatment, and/or recovery efforts to address the opioid crisis?
2. What have been the barriers and facilitators to conducting prevention, treatment, and/or recovery efforts to address the opioid crisis?
3. What structures, processes, and policies are currently in place at the state or community level to respond to the opioid crisis (e.g., Good Samaritan laws, naloxone access laws [i.e., standing orders/collaborative practice agreements] and/or distribution sites, access to PDMP for surveillance, planning and clinical purposes, integrated community care models, technical assistance training)?
4. How has capacity and need for prevention, treatment, and recovery efforts changed over time (e.g., addressing geographic variations, addressing population demographic characteristics)?
5. What EBP(s) were implemented in Year One and Year Two and for which population(s)?

6. Assessment of Substance Abuse Block Grant (SABG) measures at baseline, Year One, and Year Two.

SABG measures include:

- Number of people who receive opioid use disorder (OUD) treatment;
- Number of people who receive OUD recovery services;
- Numbers and rates of opioid use (prescription opioid use/heroin);
- Numbers and rates of opioid overdose-related deaths;
- Number of providers implementing MAT; and,
- Number of OUD prevention and treatment providers trained, to include: Nurse Practitioners, Physician Assistants, as well as physicians, nurses, counselors, social workers, case managers, etc.

7. With respect to this specific funding, what were the barriers and facilitators to continuing prevention, treatment, and/or recovery services or strategies to address the opioid crisis? Did these barriers and/or facilitators change over time (e.g., baseline, Year One, Year Two)?

Summative Evaluation (Activities will focus on up to 10 sentinel states)

The summative evaluation component will focus on questions such as:

1. What are the treatment utilization patterns within the 10 selected states (e.g., number of clients receiving treatment, treatment modality, mean/median time in treatment, number of injections administered)?
2. What harm reduction, abstinence, and primary and secondary prevention activities have been implemented at each of the clinics within each of the 10 sentinel states (e.g., number of clients with reduced drug use [all drugs and by specific drugs], number of clients that stopped using drugs and median/mean time of abstinence, number of clients retained in treatment)?
3. How is recovery assessed in each of the states/communities? How many clients report being in recovery at six months/one year/18 months? What recovery supports is identified as being most helpful? What are the barriers and facilitators to recovery and implementing recovery supports?
4. How have clients been engaged in psychosocial services, if any?

Major Core Tasks: *(Add/delete rows as needed)*

Major Tasks (Core Work)	Funding %	Conference/Exception Approval Required? Yes or No
Management	10%	
Evaluation Design/Data Collection Instruments	5%	
OMB Clearance	1%	
Data Collection	40%	
Data Analysis	20%	
Briefings/Presentations	10%	
Reporting	14%	

Key Deliverables: *(i.e., what products and/or services the contract is purchasing)*

- Work plan
- Reports (Semi-annual and final)
- Evaluation design
- Data collection instruments
- Data collection – client level data, community-level data, state-level OUD data
- Needs assessment, state strategic plan to address gaps in prevention, treatment, and recovery
- OMB materials
- Semi-annual briefings

Optional Task: *(Add/delete rows as needed. NOTE that non-SAMHSA funds can only be for optional tasks.)*

Brief Description of Optional Task	Center/Office or Fed Partner has FY 2017 funding? Yes or No	If yes, Amount and Source of FY 2017 funds	Conference/Exception Approval Required? Yes or No

8. Justification and/or Special Considerations: *(Discuss any special issues or considerations for this procurement, e.g., conference or IT review/approval requirements, including dates affecting timing of award; need to wait for resolution by Congress on parameters; questions or issues raised by OMB or ASFR; policy or program changes from current practice; or political sensitivities.)*

Special considerations have been separated into groups as identified and described further below.

- **OMB Clearance** - The ability to collect data in the short timeframe of the Opioid STR is limited and will require an emergency clearance so that data can be collected in a timelier manner; however, the likelihood of obtaining such a clearance is unknown. If the clearance is not received, the timeline for receiving full OMB clearance would present significant barriers for data collection during the timeframe of the Opioid STR and could limit the ability to collect and report on outcomes. To assess outcomes and whether a state's activities (i.e., implementation of a program/treatment modality/EBP, or more) had an effect at the individual (client) level, data collection would have to begin at or near program implementation and baseline information would have to be collected on participants. Unless OMB approval and data collection methods are identified near the time that states receive funding and when they begin to implement their program's data collection efforts, evaluation activities could begin months after initial program implementation, which would result in the loss of baseline data at the client and programmatic level beyond that which is required to be reported per the FOA. CBHSQ recommends seeking emergency OMB clearance; the only precedent for this action is SAMHSA's suicide hotline. It appears that this work would rise to the level of meeting the criteria for emergency clearance.
- **Type of evaluations to be conducted** –Obtaining outcome information would require collecting data from the same individuals (clients) during and beyond the timeframe of the grantee funding. The funds available may not facilitate a prospective study (following individuals beyond the Opioid STR funding). To potentially obtain outcome information within the timeframe of study, sentinel states and prevention, treatment and/or recovery providers (individual providers and/or organizational providers [clinics]) within those states will be chosen from each of the 10 HHS regions. There are potential issues with collecting data at baseline and throughout the study; according to the Opioid STR FOA states that will be reporting limited data. Moreover, to determine individual outcomes, specific information about the types of services (or activities) implemented (including which EBPs were chosen and the fidelity to those EBPs) for which populations, and other individual-level information is necessary. Thus, data collection will need to include the provider/clinic level and individual-level data. Consent of individuals to be included in the study will be necessary and some clinics/providers may require an Institutional Review Board to participate in data collection and data sharing. In addition, the small number of participants that could be included to obtain outcomes, combined with the timeframe for data collection and reporting may limit the ability to

discern outcomes and generalize conclusions about the impact of the Opioid STR on broader populations and subpopulations of interest.

To obtain information for the summative evaluation, even with the special considerations just described, fewer states and resources would be invested in conducting formative and process evaluations which will further limit the generalizability of the findings.

Additionally, available outcome (summative) information for non-sentinel sites will only provide basic data/information and be aggregated to the state level so only large changes that occurred in the short timeframe of the Opioid STR would likely be found.

Surveillance information, and each state's capacity to report information as required by the FOA, would provide some information on behavioral health reporting and the potential facilitators and barriers that each state experiences which would help us understand the opioid epidemic and subsequent state responses, but would not directly suggest individual-level impacts (unless, for example, state-level data included information such as hospital admissions [with or without emergency department admissions], emergency department discharges, and/or PDMP information which could be dis-aggregated from the state to the clinic or individual level). Determining whether any changes that occurred within the state could be attributed to the program(s)/EBPs, or other prevention, treatment, or recovery services would be difficult to determine.

- **Program services/practices** - Based on the FOA, only general guidelines were provided on allowable activities (e.g., train practitioners and providers, support access, address barriers, increase capacity, distribute naloxone) but recommendations on how these activities should be implemented, and which, if any, EBPs to use was minimal. The lack of specificity in the FOA increases the variability of how prevention, treatment, and recovery services are implemented and which EBPs are selected and implemented within and across each state/territory. Similarly, specificity on the type of data and frequency of reporting is not included in the FOA except through mention of the required needs assessment and approximately six required performance measures. No other requirement for reporting is included, which presents challenges as described above.
- **Sub-recipient number** - Given the diversity of allowable activities and the large number of possible grantees (all states and territories), some of the evaluation planning will be impacted by the number of opioid treatment providers within each state that ultimately receive funding. As learned during the CCHBC/223 evaluation planning, various factors affected the number of grantee sub-recipients selected; should a small pool of providers receive funding, data collection and the overall evaluation will look quite different than a scenario in which a very large number of providers are funded, with each engaging in their own set of allowable activities. Staff has no means of assessing this situation until the awards have been made. For example, for a program such as the 10% set-aside, the evaluation (funded at \$1 million) has elected to focus only on a small subgroup of states engaging in a particular model of first episode psychosis (FEP) intervention, not the full range of FEP activities allowable under the funding.

9. COR/ACOR Information

Name of COR: Laura Jacobus-Kantor

Name of Center/Office and Division/Branch: CBHSQ/DEAQ/QEPB

Phone number for COR:

Level of COR Certification: COR-II

Please explain reasoning for choosing said COR: COR has served as COR on two separate evaluation contracts previously (PBHCI, MHFA) and served as an evaluation desk officer providing evaluation expertise to numerous evaluation contracts that have been awarded to conduct evaluations of grantee cohorts at the individual and cross-site levels.

ACORS

Name of Alternate COR: Minnjuan Flournoy
Floyd

Name of Center/Office and Division/Branch: CSAT

Phone number for Alternate COR:

Level of COR Certification: COR-II

This planning document has been reviewed and cleared by:

Name	Signature	Date
Laura Jacobus-Kantor, COR, CBHSQ/DEAQ/QEPB	<i>Laura Jacobus-Kantor</i>	1/19/17
Tom Clarke, ACOR, CSAP	<i>Jovida B. Hook for Thomas Clarke</i>	1/19/17
Sherrye McManus, ACOR, CSAT		
Frances Harding, Director, CSAP	<i>for: Frances T. Harding</i>	1/19/17
Kimberly Johnson, Director, CSAT	<i>[Signature]</i>	1/19/17
Daryl Kade, Director, Director, CBHSQ	<i>[Signature]</i>	1/19/17
Monica Feit, Policy Lab/OPPI Director		
Deepa Avula, Director, OFR		

Kana Enomoto, Deputy Assistant Secretary, SAMHSA	<i>[Signature]</i>	2/1/17
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10. Follow-up Notes (if needed) TO BE COMPLETED BY OPPI/OFR:

Attachment 3

Evaluation Final Report– Proposed Standard Language

Evaluation Final Report: The contractor will submit a draft version of the evaluation final report to the COR no later than 90 days prior to the expiration of the task order period. A revised version of the report will be due no later than 14 days after receiving feedback from the COR/EDO.

At a minimum, the evaluation final report will include:

- An executive summary (not to exceed two, single spaced pages), which will include, at a minimum, a description of the program, the evaluation design, key evaluation results, limitations of the study, and recommendations for SAMHSA policies and programs;
- An introduction that discusses necessary background information, including a review of the literature, an overview of the program, and a review of previous evaluation findings (if applicable);
- A discussion of the evaluation design, including a description of the evaluation questions, methods, analytic techniques, and data sources used to address each of the evaluation questions;
- Results from the evaluation that discusses evaluation findings separately for each evaluation question;
- Limitations of the evaluation;
- Conclusions and implications of the evaluation; and,
- Appendices that include technical and other documents relevant to the evaluation, including the design, methodology, and analytic techniques that are more appropriate to include as an appendix than as the body of the report.

The contractor shall submit a 508-compliant version of the SAMHSA-approved evaluation final report to the COR no later than 14 days prior to the expiration of the task order period. At a minimum, each evaluation’s executive summary will be posted on SAMHSA’s Intranet.

Attachment 4

Evaluation Data Files– Proposed Standard Language

All information and materials, including the data developed under this task order are the property of the Government, and shall be delivered as part of this task order. Relevant data to be delivered to the Government include all analytic data files (quantitative and qualitative), data dictionaries, code books, and annotated syntax. All data files will be delivered electronically in password encrypted files via a secure file transfer protocol (SFTP). If an SFTP is not available, password encrypted files will be provided on CD-ROM and mailed to the SAMHSA COR.

The contractor shall provide the COR with all evaluation datasets and materials **no later than 30 calendar days** prior to the expiration of the task order. All datasets will include a codebook and data dictionary (submitted in MS Word, Excel, or ASCII format); the original (raw) and final datasets used to conduct data analyses included in the final report; and, all statistical and programming language used to create the datasets, including any rules used to clean the data, normalize results, and/or omit outliers, and conduct the analyses of the data. All datasets submitted by the contractor will meet all SAMHSA requirements for de-identification of individuals.

Attachment 5

Evaluation Final Report Clearance Form

1. Draft Version of the Evaluation Final Report

The contractor submitted a draft version of the evaluation final report at least 90 days prior to conclusion of the task order or contract?

_____ COR initials/date

2. Draft version of the Evaluation Final Report Review

(Note: Review occurs concurrently, as ordered. If a review is not finished within two weeks of being received [unless out of office], review moves forward to next concurrent review. All reviews should be provided to the COR and EDO via email.)

COR, EDO, CMO, OC, the center director, and CCERB, if applicable, have reviewed a draft version of the evaluation final report and provided feedback to be given to the contractor through the COR?

1. _____ COR initials/date _____ EDO initials/date

2. _____ OC initials/date _____ OCMO initials/date

_____ CD initials/date

3. _____ CCERB initials/date (if applicable)

3. Evaluation Final Report Publication

(Note: Initial in only one column; Option One or Option Two. If a review is not finished within two weeks of being received [unless out of office], review moves forward to next concurrent review. All reviews should be provided to the COR and EDO via email.)

Option 1. Release Full Report

Members listed below have reviewed the final version of the evaluation report and agree to release the full version of the report.

1. _____ COR initials/date
 _____ EDO initials/date

2. _____ OCMO initials/date
 _____ OC initials/date
 _____ CD initials/date

3. For significant evaluation activities only, the CCERB has reviewed the final version of the evaluation report and agrees to release the full version of the report.
 _____ CCERB initials/date

Option 2. Release Executive Summary

Members listed below have reviewed the final version of the evaluation report and agree to release only the Executive Summary of the report.

1. _____ COR initials/date
 _____ EDO initials/date

2. _____ OCMO initials/date
 _____ OC initials/date
 _____ CD initials/date

3. For significant evaluation activities only, the CCERB has reviewed the final version of the evaluation report and agrees to release only the Executive Summary of the report.
 _____ CCERB initials/date

4. Publication

OC has received a 508 compliant version of either the evaluation final report or the executive summary (whichever is being released) for publication on the SAMHSA website?

_____ COR initials/date