SUPPORTING STATEMENT: PART A

Medication-Assisted Treatment (MAT) for Opioid Use Disorders Study

OMB# 0920-XXXX

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A. JUSTIFICATION

Summary Table

- Goal of the study:

Conduct an epidemiologic study to assess the real-world client outcomes of three types of Medication-Assisted Treatment (MAT) and counseling without medication for individuals with Opioid Use Disorder (OUD). This study will also examine the contextual, provider, and individual factors that influence treatment implementation and client outcomes.

- Intended use of the resulting data:

Data collected will be used to assess the impact of MAT or counseling without medication along with the contextual, provider, and individual factors that influence the implementation of four treatments as well as client well-being, across these treatments, over a 2-year period.

- Methods to be used to collect:

This observational study will use longitudinal quantitative surveys and qualitative focus groups to collect data on patients and treatment facility staff.

- The subpopulations to be studied:

Individuals starting a new treatment episode for OUD enrolled in MAT (MMT, BUP, or NTX) or counseling without medication (COUN). Staff at participating treatment facilities such as site administrators, doctors, clinicians, nurses and counselors.

- How data will be analyzed:

The study will use a mixed-methods approach using quantitative methods such as multilevel latent growth models, propensity score matching, latent class analysis and advance mediation analysis and qualitative methods such as interactive coding and analysis for common themes.

A.1 Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request. The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval to initiate data collection for the Medication-Assisted Treatment for Opioid Use Disorder (OUD) Study (here after, the MAT Study). Approval is requested for 3 years.

This data collection effort is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) 280-1a (Att. 1). This data collection effort is necessary and unique. To better address the opioid use epidemic and the increasing public health risk due to opioid-related overdoses it is necessary for the CDC to use this data collection to assess MAT treatment and counseling without medication for OUD in real-world settings. The information gained from this data collection will help inform policy makers, communities, and providers on how individual characteristics and contextual factors may impact client outcomes.

The United States is in the midst of a public health emergency, and control of the opioid overdose epidemic is a priority for the White House, the Department of Health and Human Services, and the CDC. On October 26, 2017, President Donald J. Trump instructed the Administration to use all appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic and the Secretary of HHS declared the opioid crisis a public health emergency. In 2015, there were over 52,000 drug overdose deaths in the United States. Provisional data from CDC's National Center for Health Statistics indicate that deaths will climb to unprecedented levels in 2016 (over 64,000). Opioids are involved in approximately 60% of fatal drug overdoses, and this is a substantial underestimate because the specific drug causing an overdose is not listed on death certificates for 1 in 5 drug overdose deaths (Rudd et al, 2016).

OUD has been identified by DHHS as part of the national opioid overdose crisis (ASPE 2015). OUD is a problematic pattern of opioid use that causes significant impairment or distress characterized by unsuccessful efforts to control use and failure to fulfill family, social, work-related, or school-related obligations. About 2 million people aged 12 or older in the United States have OUDs related to prescription opioids and almost 600,000 have OUDs related to heroin use (CBHSQ, 2016). Many of these people do not receive OUD treatment (CDC, 2017, CBHSQ, 2016). Further, we know little about the ideal care regimen for various sub-populations (Pacific Northwest Evidence-Based Practice Center, 2016).

The U.S. Food and Drug Administration has approved three classes of medications for the treatment of an OUD: methadone maintenance therapy (MMT), buprenorphine (BUP), and naltrexone (NTX) (Dunlap and Cifu, 2016). Few studies are available to help patients and providers make informed decisions about the risks and benefits associated with the different MATs (Kampman and Jarvis, 2015). Understanding the outcomes associated with different types of MAT is crucial because differences in pharmacological characteristics and routes of administration across medications, patients' physiological responses to medication, patients' underlying or co-occurring conditions, and provider or site characteristics all influence how patients respond to the treatment and, thus, their long-term treatment success.

Aligned with CDC's role in advancing public health practice, this observational cohort study, will yield important information about MAT implementation and the patient, provider, and site factors that can influence MAT outcomes. The study is heavily informed by and expands upon the MAT randomized controlled trials conducted by the National Institute on Drug Abuse (NIDA), and builds upon the practice-based efforts of the Substance Abuse and Mental Health Services Administration (SAMHSA) to evaluate the impact of their programmatic funding.

To help understand the factors involved in successful treatment, the CDC is conducting a study of 60 OUD treatment facilities and four primary care facilities located in 11 metropolitan statistical areas (MSAs) across the United States. The study aims to enroll 3,560 patients across all sites. Data will be collected from patients with OUD enrolled in MAT (MMT, BUP, or NTX) or counseling without medication treatment over a two-year period, regardless of retention in treatment. These respondents are referred to as patients throughout this document. Data will also be collected from staff at participating treatment facilities such as site administrators, doctors, clinicians, nurses and counselors; treatment facilities may select the type of staff who participate in data collection activities. These respondents are referred to as treatment facility staff throughout this document.

Prior randomized controlled trials have demonstrated that MAT with methadone, buprenorphine, or naltrexone with counseling is the most effective treatment for opioid use disorder (Weiss et al., 2015). MAT is associated with decreases in withdrawal symptoms, reductions in opioid use, reductions in risk behaviors that can transmit HIV and HCV, reductions in crime and recidivism, and decreases in the likelihood of overdose death (Thomas et al, 2014;

Thomas et al, 2014). Despite this effectiveness, MAT remains vastly under-utilized. According to SAMHSA's Treatment Episode Data Set (TEDS), the proportion of heroin admissions with treatment plans that included receiving MAT decreased from 35% in 2002 to 28% in 2010. HHS estimates that in 2014, 1.2 million people eligible to receive MAT for an opioid use disorder did not receive treatment.

Recently, there has been a concerted federal effort to expand use of and access to MAT. This includes expanding the use of MAT within opioid treatment programs, increasing the number of physicians who can prescribe buprenorphine in the office-based setting, and expanding the use of long-acting injectable naltrexone. The purpose of this mixed methods study is to follow a cohort of participants receiving MAT over a two year period to better understand the relationship between MAT implementation and outcomes. The MAT Study will extend previous research by 1) assessing the treatment, individual, and contextual factors that influence implementation and outcomes in real-world settings; 2) targeting a larger sample size (n=3,560) than previous studies; and, 3) providing a longer follow-up window (i.e., 24-month follow-up period with patients) than previous studies so that we can collect data on short- and longer-term outcomes and relapses. Outcomes from this study are not design to identify or guide policy. CDC has collaborated with other relevant federal agencies (See Section A.8) to avoid duplication and maximize efficiencies in data collection.

A.2 Purposes and Use of the Information Collection

The MAT Study is guided by four overarching evaluation questions listed in ***Exhibit 1***. These questions drive the research design, and this data collection effort was developed to specifically address these evaluation questions.

Exhibit 1. Evaluation Questions

Evaluation Questions
What outcomes are associated with participation in MAT (BUP, MMT, NTX) and COUN?
What are the program factors that are associated with positive MAT outcomes?
What are the characteristics of program participants that are associated with positive MAT outcomes?
Does MAT improve the health-related quality of life of people with an OUD?

BUP = buprenorphine; COUN = counseling without medication; MAT = medication-assisted treatment; MMT = methadone; NTX = naltrexone; OUD = opioid use disorder.

This data collection effort captures a series of outcome measures including the associated benefits (e.g., reductions in morbidity, mortality, and drug overdoses; improvements in socioeconomic outcomes and health-related quality of life [HRQOL]) and potential risks (e.g., side effects, diversion potential) of each treatment alternative. We will also collect data on antecedents of OUD, client factors that might also affect OUD treatment (e.g., age, gender, substance use history), barriers to care (e.g., health insurance coverage, provider location), and program characteristics that could affect OUD treatment outcomes.

To operationalize these overall evaluation questions, the CDC has identified 18 essential study measures that will be captured by this data collection as shown in ***Exhibit 2***. The selected outcome measures are necessary as they reflect the outcome measures used by the existing literature on MAT and OUD treatment and the outcomes of interest to policy makers, communities, OUD treatment providers and their patients. Measures related to treatment intensity, treatment course and adverse substance use outcomes provide the basic measures to determine if patients are obtaining and remaining in treatment while achieving positive outcomes such as reduced drug use and averted overdoses. As OUD is best understood as a chronic condition, social, quality of life and medical outcomes (such as employment, ability to perform everyday tasks comfortability and negative HIV tests) are critical to understanding the medium and long-term impacts of treatment. Lastly, measures of treatment access and client treatment experiences help determine if patients will seek out and stay in treatment.

Exhibit 2. Study Measures

	Domain / Study Measure
	Treatment Intensity
1	Number of days/weeks participating in treatment
2	Number of counseling sessions attended
	Adverse Outcomes from Opioids
3	Number of substance use (and opioid)–related emergency department visits
4	Number of substance use (and opioid)–related hospitalizations
5	Number of non-fatal drug (and opioid) overdoses
	Substance Abuse Outcomes
6	Number of calendar months with at least one negative opioid urine test, and no positive urine tests for other substances (excluding MAT drug)
7	Number of days/weeks abstinent from opioids (excluding MAT drug), self-report

	Social Outcomes
8	Employment status (yes/no and length of employment)
9	Number of diversion incidents
	Health Related Quality of Life
10	Number/rate of QALYs or DALYs
	Adverse Treatment Outcomes
11	Number adverse events associated with medication
	Medical Outcomes
12	Number of positive HIV tests
13	Number of positive HCV tests
14	Number of positive birth outcomes among women who have substance use disorders and are pregnant
15	Number of positive birth outcomes among women who have an opioid use disorder and are pregnant
	Access to Medical Treatment
16	Access to primary care medical treatment (on client roster with a primary care physician, at least one visit in the past year)
	Factors Facilitating Treatment
17	Access to reliable transportation (e.g., car ownership/leasing, monthly public transportation pass)
	Treatment Course
18	Number/rate of subsequent treatment episodes

DALY = disability-adjusted life-year; HCV = hepatitis C virus; MAT = medication-assisted treatment; QALY = quality-adjusted life year.

The following section details the purpose of the information collected, how it is collected, by whom and how frequently.

Patient Screener Form

The Patient Screener Form collects recent OUD treatment initiation and client demographic information. This information is necessary to determine which treatment type (MMT, BUP, NTX, or COUN) a client is initiating. Demographic information on race, ethnicity and gender identity will be used to track recruitment diversity.

The Patient Screener Form will be completed once by all patients recruited for the study with the assistance of an RTI International (RTI) Field Interviewer (FI) through a web-based data collection tool.

Patient Check-In

The Patient Check-In Questionnaire (Att.5) collects client outcome measures including current OUD treatment status, substance use, physical health, and criminal behavior. These questions are a subset of those used in the Patient Questionnaire (described below). This information is necessary as it allows for essential client outcome measures to be collected while patients are expected to be actively engaged in treatment. The Patient Check-In Questionnaire will also provide critical data points in this study, which follows patients over 2 years, when combined with the Patient Questionnaire data.

The Patient Check-In is completed twice by all patients enrolled in the MAT Study at 3 and 6-months post enrollment. The questionnaire can be completed independently by patients through a web-based tool or with the assistance of an RTI FI.

Patient Questionnaire: Baseline, 12-Month and 24-Month Follow-Ups

The Patient Questionnaire will capture detailed information on client characteristics and outcomes which allow the study to comprehensively measure a wide range of client outcomes over a two-year period. Questions are drawn from established tools used regularly with individuals seeking and obtaining substance use treatment. The majority of the scales and sub-scales included in the questionnaire have demonstrated reliability and validity in prior studies as indicated in ***Exhibit 3***. Patient demographics will only be collected at baseline while the remaining measures will be collected at baseline, 12, and 24 months. This repeated collection over time is critical to the data collection's design and will allow the study to more completely answer the evaluations questions. The topic areas and their associated measures listed in Exhibit 3 will be used in two ways: 1) as outcome measures to help understand the positive and negative impacts of treatment or the lack of treatment and 2) as control variables to understand how client characteristics influence client outcomes. The outcome measures listed in Exhibit 2 are necessary to document both the immediate outcomes such as reduced substance use well as longer term outcomes such as employment and quality of life. Collecting the control variables listed in Exhibit 3 is necessary to better understand how client characteristics such as childhood trauma, mental health disorders, and physical health mediate or moderate a client's treatment outcomes.

The Baseline Patient Questionnaire will be collected within a month of enrollment in the study. Patients will complete questions through a web-based tool and collection will be

supported by an RTI FI who will help the client complete the questionnaire as needed. Prior to completion of the Baseline (Att. 6) the interviewer requests that a patient enter his/her Social Security Number (SSN) through a secure web-based tool. The SSN query is a short and separate instrument with a visible note that the collection of SSN is voluntary (Att.6a). The patient is clearly informed in the ICF, orally by the Field Interviewer, and again on the query screen that he/she may refuse to provide SSN. There is a precedent for federal agency collection of study participants' Social Security Number. For example, the National Longitudinal Survey of Adolescent Health (Add Health), sponsored by NIH, obtains SSN for follow-up. The National Health Interview Survey is not a longitudinal follow-up and uses the last 4-digis to match previously obtained records, rather than for tracking participants.

The client's SSN and other contact information is critical to the success of this longitudinal study and without it the two-year client follow-up data collection will not be possible. SSNs will only be used for tracking patients in vital records, such as the Social Security Death Index, and using SSNs with an individual's birthdate is the only means to get this information quickly (without an SSN, death records may not be confirmable for three years) and reliably (Corsi et. al., 2006). More broadly, patients with OUD face a chronic disorder and their outcomes must be tracked over time yet tracking patients with OUD is especially difficult as the population is often engaged in illegal drug use and lack stable connections to public society (see Section A.9 for additional details). Using SSNs to track these patients over time is a vital tool to real-world data collection efforts (Farabee et. al., 2016). One of the significant contributions of this study is the tracking of patients over a two year period regardless of treatment status. This will increase our understanding of how and why people are retained in, drop out, and often, re-enter treatment. Without the social security numbers, it will be extremely difficult to track this transient population over the two year period and will we jeopardize a key benefit of this study. If FIs lose contact with a client, they will seek to relocate the client and reestablish contact. Methods to relocate clients include emailing, sending a certified letter to their home; reaching out to alternative contacts (e.g., parent, friend) obtained during enrollment; driving by the client's home; and checking local data sources (e.g., newspapers, court dockets).[1] The client will

1 RTI will ask clients what methods of contacting they are agreeable with, and we will only use those methods. For example, a client must agree to receiving mail at the provided address.

also be referred to RTI's Tracing Unit, which conducts online searches (e.g., U.S. Postal Service change-of-address records, DMV records, credit reports, judicial arrest records) as well as checking Vital Statistics for deaths. Tracking and tracing efforts have succeeded in retaining up to 10% of lost subjects on similar studies.

The Patient Questionnaires are collected at 12 and 24 months after the baseline questionnaire is completed. Using a web-based tool, a client can complete the questionnaire independently; if needed an RTI FI will be available to assist the client.

Exhibit 3. Patient Questionnaire Measures

Topic Area	Measures
Outcome Measures	
Treatment Status	Determines if the respondent is still participating in OUD treatment. Identifies characteristics of the client's index treatment (treatment episode during which they enrolled in the MAT Study) and as well as pre- and post-index treatment received.
Substance Use	Questions on substance use are derived from the 2015 National Survey on Drug Use and Health (NSDUH) and ask the respondent about their use of substances (i.e., opioids, heroin, illicitly-made fentanyl, stimulants, sedatives, neuropathics, marijuana, cocaine, methamphetamine, krokodil, synthetics, inhalants, alcohol, and tobacco) over the last 12-months, 90 days, 30 days, and while in treatment.
Opioid Quit Attempts	Questions on opioid quit attempts are derived from the Center for Substance Abuse Treatment (CSAT, 2016) measures. These questions address the number of times the client has attempted to quit using opioids, number of times the client quit using opioids for more than five days, and the longest amount of time the client quit using opioids.
Crime and criminal behavior	Questions derived from the CSAT Client Government Performance and Results Act (GPRA) Tool (2016) include items about client's lifetime arrest history, most recent arrest, arrests over the last year, and current legal status.
Drug Overdose	Questions from the Overdose Baseline Questionnaire (Open Health Foundation, 2013) address the number of drug overdoses, the drugs involved, use of ambulance services, and use of naloxone. These are asked for lifetime, past 12 months, and past 90 days.
Health Outcomes and Quality of Life Years (QALYs)	Health outcomes are derived from the CDC Healthy Days measures and the EQ-5D (2016). The Healthy Days measures, found within the Behavioral Risk Factor Surveillance System (BRFSS), provide information on participants' health-related quality of life (HRQOL) through self-reported questions regarding participants' health behaviors, impairments, and symptoms. The EQ-5D™ is a standardized instrument that was designed by the EuroQol Research Foundation and allow development of QALYs.
Substance Use Treatment	Questions derived from the 2016 CSAT GPRA Tool and NSDUH addresses treatment, including detoxification, hospital care, emergency department services, self-help meeting services, alternative care, and primary care services. For MAT, specific sets of questions are based on question phrasing used in NSDUH (NSDUH, 2015).
Labor Market	Questions ask about client's current employment, income level, sources of income, absences from work, and absences from work related to opioid use.
Control Variables	
Demographics (most completed at Baseline	The questions include age, sex, ethnicity, race, sexual orientation, marital status, Zip Code, living arrangements, type of residence (independent or controlled), education, and military service. Two questions, derived from the recommendations of The Williams

Topic Area	Measures
only)	Institute GenIUSS Report (2014), are used to assess gender: the first asks patients for their assigned gender at birth, while the second asks patients for their current gender identity.
Social Support	Social support is measured using the Multi-Dimensional Scale of Perceived Social Support, developed by Zimet, Dahlem, Zimet, and Farley (1988).
Substance Abuse Stigma Perceptions	Questions regarding knowledge, attitudes, and beliefs about substance use come from the Substance Abuse Self-Stigma Scale (SASSS) item pool (Luoma et al., 2013) and include items on self-devaluation, fear of enacted stigma, and stigma avoidance and values disengagement.
Childhood Trauma	Questions from the CDC's BRFSS (CDC, 2015) include questions on potential negative experiences during childhood.
Physical Health	Questions from NSDUH (2015) include questions on lifetime diagnoses, history of HIV/AIDS, and HEP-C testing and outcomes.
Pregnancy	Questions ask about participant's history of pregnancy, participant's opioid use while pregnant, and if the participant's newborn was diagnosed with neonatal abstinence syndrome.
Mental Health Disorders and Mental Health Status	Three scales, the Perceived Stress Scale (Cohen, Kamarck & Mermelstein, 1983), Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001), and PC-PTSD scale (Prins et. al., 2015).
Suicidal Ideation and Attempts	Questions from the 2015 NSDUH ask the about the client's suicide ideation and attempts over the past 12 months.

PTSD = posttraumatic stress disorder.

Patient and Treatment Facility Staff Focus Groups

To better understand the often-complex facilitators and barriers to obtaining, remaining in, and providing MAT and counseling without medication, the MAT Study will also conduct separate Focus Groups with patients (Att. 7) and treatment facility staff (Att. 8). Patient Focus Groups will collect qualitative information on decisions to enter treatment, treatment access, barriers and facilitators to treatment, and experience with providers. This information will help provide context to the quantitative data on client outcomes. Similarly, the Treatment Facility Staff Focus Group will collect qualitative information on the treatment facility work environment, staff backgrounds with MAT or counseling without medication, barriers and facilitators to treating OUD patients, and staff opinions on effective OUD treatment. This qualitative data will provide further context to understand the client impressions of MAT and counseling without medication as well as further context through which to better interpret client outcomes.

Both the Patient and Staff Focus Groups will be conducted annually for three years. There will be three Patient Focus Groups (Att. 7) per year, one for METH/BUP patients, one for NTX patients, and one for counseling only patients. Each Patient Focus Group will consist of up

to 9 patients. Each staff Focus Group will consist of up to 9 clinical staff. All Focus Groups will be conducted virtually via tele-conference.

Participants for the Patient Focus Groups (Att. 7) will be selected among those patients enrolled in the MAT Study. Patients will be asked during the administration of the Client Questionnaire (Att. 6) if they will consider participating in a telephone focus group. Patients will be selected purposefully to ensure representation by key groups or characteristics. RTI will track who participates in each focus group and each patient will only be eligible to participate once. Within each group, the patients will be recruited to represent a diverse range of client-level characteristics, namely sex, age, residence (i.e., rural or urban), type of opioid (i.e., prescription opioid vs. heroin), and route of administration (i.e., injector vs. non-injector). RTI will use data on patient characteristics from the baseline client questionnaire to inform our participant selection. Invitations will be sent out via email to a small number of patients from among those who agree to be contacted.

All data collected are designed to be disseminated publicly to practitioners, individuals with OUDs, researchers, and lay audiences. The data collection will inform best practices, build the evidence base, and provide de-identified datasets for additional research. Dissemination activities are discussed fully in Section A.16. Data collection will be conducted by RTI International under contract HHSD20002013M53964B and is funded under a 4.5-year, fixed-price budget with payment made for specific project deliverables.

A.3 Use of Improved Information Technology and Burden Reduction

Information technology will be used, as appropriate, across all data collection activities. Its use will reduce respondent burden, increase privacy, and streamline data collection and processing across the 64 treatment facilities. The Patient Screener Form, Patient Check-In and Patient Questionnaires will all be administered using a secure laptop computer, and each tool will be web-based so that RTI FIs, treatment facility staff, and patients can easily use it. The questionnaires will be programmed with automatic skip patterns, which will be critical in allowing patients to quickly answer only the questions that are relevant to their experiences; for example, only answering questions related to the drugs they have used instead of responding to questions on all drug types. The automated questionnaires will also allow patients the privacy to complete sensitive questions independent from the FI. Patient and Staff Focus Groups (Att. 7

and 8) will be virtual and will use telephone-based conference tools to reduce client and site burden and maintain participant privacy.

All data will be securely transmitted with web-based tools being hosted on secure RTI servers; further, client-identifying information will not be collected or stored with client responses. To support patients without access to computers and other devices, RTI FIs will provide all the necessary technology to complete the questionnaires via in-person administration.

A.4 Efforts to Identify Duplication and Use of Similar Information

The MAT Study design and protocols have been reviewed and shared with colleagues from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse (NIDA) to help ensure the data collected by the MAT Study avoids duplication. CDC has collaborated across federal agencies through a federal panel (see ***Section A.8)*** and other communications with federal staff, including Dr. Jones at the Office of the Assistant Secretary for Planning and Evaluation, Dr. Campopiano at SAMHSA, and Dr. Tai at NIDA**.** SAMHSA's Opioid State Targeted Response (STR) Evaluation ((OMB#: 0930-0379) will be collecting data from opioid treatment facilities and their patients receiving Opioid STR funding or funded treatment services. The Opioid STR evaluation will focus data collection on better understanding the treatment services provided by treatment facilities before and after Opioid STR funding is received. Patients receiving Opioid STR funded services will be asked to complete the SAMHSA CSAT's GPRA tool which collects information on substance use, treatment services and general demographic information at baseline, discharge and 6-month post baseline.

While both the Opioid STR evaluation and the MAT Study examine similar populations and topics, the data collected differ significantly. The Opioid STR evaluation and the data collected for it are focused on assessing the impacts of the Opioid STR funding while the MAT Study collects data on the current implementation of OUD treatment across the United States. For client level measures, the MAT Study plans to collect data measures specific to individuals obtaining OUD treatment at 12- and 24-month follow-up periods which will help capture longer term outcomes not covered by the GPRA data used in the Opioid STR evaluation. The MAT Study continues to track patients for two years, regardless of whether or not they are retained in

MAT or counseling without medication to better understand the trajectory of and recovery from OUD.

Other studies of people with OUD include Novak et al., 2015 which estimated overall prevalence of misuse and abuse and examined psychosocial characteristics of individuals who inject drugs, including differences among methadone and buprenorphine. However, less than half of the study's sample were in treatment at baseline and the study was limited to the San Francisco area. Furthermore, the study did not provide extended follow-up of patients and it did not include other OUD treatment options (e.g., NTX, COUN). Novak et al., 2009 examined the link between physical pain and non-prescription analgesic use. This study relied on data from National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) sample which is a nationally representative sample including individuals within and without treatment. Although the study examined some of the same factors as in the MAT study, this study was not an examination of OUD treatment.

A.5 Impact on Small Businesses or Other Small Entities

Data will not be collected from small entities.

A.6 Consequences of Collecting the Information Less Frequently

This data collection effort is conducted over an expected 3-year period with multiple points of data collection. The data collection is necessary to help the CDC better understand current efforts to address OUD and the opioid epidemic. Understanding how real-world treatment efforts impact client outcomes and how those outcomes maybe influenced by client characteristics is critical to the agency's goals of controlling and preventing disease, including behavioral health issues.

Data collection includes the client screener (Att.4) completed once, a Baseline Client Questionnaire (Att. 6), an abbreviated 3- and 6-month Client Check-In Questionnaire (Att. 5), and full 12- and 24-month questionnaires (Att. 6). Client and staff Focus Groups (Att. 7 and 8) will also be conducted at the beginning, middle, and at the conclusion of the study. Multiple points of data collection, especially the repeated collections of the Client Questionnaire (Att. 6) and Check-In questionnaire (Att. 5), are essential to collect longitudinal data which will allow the MAT Study to measure client experiences, health behavior, and treatment outcomes over

time. Screening patients is necessary to ensure patients are eligible for the study (e.g., starting MAT or counseling without medication); it also allows for detailed contact information to be collected which will be used to contact patients during follow-ups. The repeated Client Questionnaire and Client Check-In Questionnaire are used to capture both the near-term measures and factors related to entering treatment and the longer-term outcomes after a client may have completed treatment, left treatment, or relapsed. Less frequent collection will limit the collection of longitudinal data, reduce follow-up rates and reduce data quality due to recall basis. The 24-month questionnaire is designed to provide data for a longer follow-up window than the current literature on MAT and counseling without medication and is especially needed to better understand the longer-term impacts of these treatments and the client characteristics that may influence outcomes.

Focus Groups for both patients (Att. 7) and treatment facility staff (Att. 8) will occur annually. There will be three Patient Focus Groups per year, one for METH/BUP patients, one for NTX patients, and one for counseling only patients. These annual focus groups allow for the perspectives of different patients and treatment facility staff to be regularly collected while the study is ongoing. The collection of qualitative information is necessary as it can help researchers to better understand quantitative findings. The annual Focus Groups provide the opportunity to ask questions that may elucidate client questionnaire data. For each Focus Group, new patients and treatment facility staff (i.e., a client or staff person will not participate in multiple focus groups) will be recruited to help obtain a wide range of perspectives on OUD treatment, including MAT, over time.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR1320.5

This request fully complies with all guidelines of 5 CFR 1320.5. No special circumstances are required.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.a) Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on June 19, 2017, vol. 82, No. 116, pp. 27832-3 (Att. 2). CDC received three comments to the notice. One

comment was outside the scope of the notice and was considered non-substantive. A second commenter supported the proposed study; CDC did not respond to this commenter. The third commenter was a global pharmaceutical company that provided comments related to ways to enhance the quality, utility and clarity of the information to be collected (Att.3). The proposed collection is an observational study rather than an intervention, therefore no changes were made to the data collection instruments based on this comment.

A.8.b) Efforts to Consult Outside the Agency

The study convened a federal panel on January 9, 2017, that included eight representatives from relevant federal agencies from outside CDC; ***Exhibit 4*** lists the panel's participants. The panel reviewed and provided comment on all the data collection measures and the overall approach to the study.

Exhibit 4. Federal Panel Members

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A.9. Explanation of Any Payment or Gift to Respondents

Incentives will be offered to patients completing the questionnaires included in this data collection to help ensure that patients respond at each data collection point. Given the 24-month follow-up window and the desired 80 percent response rate, offering incentives is essential to the data collection and the overall study's success. In general, studies have shown that response rates have decreased over time (Brick & Williams 2013; Curtin, Presser, & Singer 2000). This study faces three additional challenges in achieving the needed response rate. First, patients receiving OUD treatment are often hard to find and recruit; only a portion of individuals with OUD seek treatment and many may not want to identify as receiving treatment because of stigma, legal, and social concerns. Second, longitudinal surveys are valuable in tracking client outcomes over time but present challenges in data collection as individuals must be followed over time and encouraged to participate in the survey multiple times. Third, asking sensitive questions on drug use, criminal justice involvement, pregnancy and childhood trauma is burdensome on respondents but necessary to determine the effectiveness of treatment options for OUDs (James 1997).

A recent study of four alcohol and tobacco use studies showed that offering incentives increased on-time survey completion from 18% to 68% and using incentives achieved overall response rates of over 90% (Smith et. al., 2017). A longitudinal health study of individuals impacted by the 9/11 terrorist attacks in New York City found that offering a $10 incentive increased survey returns by 30% and increased the overall response rate by 18% (Yu et. al., 2017).

We have constructed this study's incentive structure to be in line with incentives approved by the OMB on similar surveys and supported by the literature. The offering of incentives for these data collection tools is comparable to incentives offered on similar data collections including the National Survey on Drug Use and Health (OMB No. 0930-0110), the National Intimate Partner and Sexual Violence Survey (NISVS) (OMB No. 0920-0822), and the Services Accountability Improvement System (OMB No. 0930-0208). All incentives provided will consist of physical or digital gift cards to a local or national store (e.g., Wal-Mart, Target,

Amazon). Patients will be offered $30 for the Baseline Client Questionnaire, $20 for each Check-In Questionnaire ($40 total), and $30 each for the 12- and 24-month follow-up Client Questionnaires ($60 total).

A $40 incentive will be given to a client participating in the Client Focus Groups and a $75 incentive will be given to a treatment staff person participating in the Treatment Facility Staff Focus Groups. While the Focus Groups are conducted virtually via conference call; patients and staff will still need to have access to a telephone located in a quiet and private setting which may require patients to travel to a treatment facility and staff to remain at offices after working hours. As Focus Groups may be scheduled outside of normal working hours, additional childcare and commuting costs may be incurred. The Staff Focus Group incentive is set at $75 to help ensure participation from highly paid professional staff such as psychiatrists, physicians, facility administrators and registered nurses.

A.10 Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does apply because the study collects personal identifiable information (PII) which is protected by the Privacy Act (1974 and 1988). The pending approval Privacy Impact Assessment (PIA) is attached (Att. 9). The applicable System of Records Notice (SORN) is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems," for which records are retrievable by SSN or by name. See Federal Register: December 31, 1992 (Volume 57, Number 252)] [Notices] [Pages 62812–62813].

Justification for the collection of SSNs and other identifiers is provided in Section A.2; all patients will be informed that SSNs will only be collected for use in tracking and contacting patients for data collection follow-up and that providing SSN is voluntary (Att. 12)

Concern for privacy and protection of respondents' rights will play a central part in the implementation of all study components. The study will require the collection of identifying information including birth date, name, contact information (mailing address, telephone numbers, email addresses) and SSN. CDC will not receive identifying information; all data provided to CDC will be de-identified by the study contractor, RTI. RTI will collect and store identifying information separately from all other client responses. Client responses will only be identified by a random ID, and the dataset linking a client's responses with the identifying information will only be accessible by the contractor's study director and managers. RTI FIs will have local access to client's identifying information but will not have access to responses. Additional details on how data security will be maintained is explained in Section B.2.

Contractor staff have extensive experience protecting and maintaining the privacy of respondent data. All data will be securely stored on a protected server to safeguard all project directories and analysis files containing completed survey data to ensure that no study data is inadvertently disclosed. In keeping with 45 CFR 46, Protection of Human Subjects, the procedures for data collection, consent, and data maintenance are formulated to protect respondents' rights and the privacy of information collected. Identifying information collection is used to track patients throughout the study. SSN collection is voluntary and will be used for tracking patients and, in some cases, used to confirm incarceration or death. All data collected will also be safeguarded in compliance with the Privacy Act of 1974 (5 USC 552a). Identifiable data, include SSNs, will be destroyed within 2 years of completion of the study. Final de-identified electronic data sets will be stored at the RTI's data repository/archiving facility in its headquarters in North Carolina for up to 10 years and at CDC facilities in Atlanta, Georgia, indefinitely.

Further, to help ensure and guarantee protecting the privacy of people enrolled in sensitive, health-related research, the study's contractor has obtained a Certificate of Confidentiality from the CDC (Att. 14). The Certificate of Confidentiality issued by the CDC protects identifiable research information from forced disclosure. It allows those on the research team who have access to the data to refuse to disclose identifying information on study participant in any civil, criminal, administrative, legislative or other proceeding. Through

informed consent process participants are informed of the Certificate's protection of the privacy of people enrolled in the study (Att. 12).

The informed consent will also meet all federal requirements and will detail the additional protections provided by the certificate (Att. 12). Additionally, several procedures will be implemented to help ensure privacy and confidentiality. First, all study staff will participate in initial confidentiality training and ongoing monitoring and supervision. Second, study staff will collect and store client-identifying information separately from other data; study staff will review data collection forms and remove any identifying information. Client-identifying information will be stored in password-protected files on secure servers to which only select study staff will have access. Identifying information will not be stored with study data, and all analysis datasets will use a randomly-generated client identifier. Third, all data will be transmitted and stored securely. All sensitive and identifying information will be stored on secure servers at RTI. The study team will only have access to data as needed through password-protected, encrypted computers.

A.11 Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

CDC has received IRB approval through RTI's independent IRB, Quorum (Att. 10). Quorum, established in 1991, is the largest independent IRB in the United States (http://www.quorumreview.com). RTI and Quorum will maintain responsibility for ensuring the study's compliance with Quorum's IRB.

Sensitive Questions

The Client Screener Form (Att. 4), Client Check-In Questionnaire (Att. 5), Client Questionnaire (At. 6), and the Client Focus Groups (Att. 7) will, by necessity, collect sensitive information about drug use, mental health, and general health as these are all outcomes of interest and are essential to the study. While patients will be asked about their drug use history, they will only be asked general questions to characterize whether a client has ever used a particular type of drug in their lifetime, in the last year, and in the last month. As such, a client's responses to questions would not link them to any specific crime. Similarly, questions on mental and general health focus on how the client has felt in the last year and the last month. If these

questions cause any distress for the client, the RTI FI will provide a telephone number for a toll-free counseling hotline (1-800-273-TALK). If a FI becomes aware of an emergency when the FI is present with the client, the RTI staff will call 911. Depending on the FI's assessment of the situation, they may suggest that the client take a break or offer to come back later. FIs are trained to remind patients that they may skip any question they want to or end their participation at any time (Att. 11).

A full Informed Client Consent (Att. 12) will be provided to the client prior to formally enrolling in the study and completing the Baseline Client Questionnaire. The informed consent form will clearly outline all risks and benefits to the client and explain what information they will be asked to provide and how that information may be used. Throughout the study, RTI FIs administrating the questionnaires will remind patients of their rights. To help maintain client privacy, all Client Check-Ins and Client Questionnaires will be conducted in a private space, and when possible, the space will be of the client's choosing. If needed, RTI FIs assisting the client in completing the questionnaires will provide a laptop or other hand-held device, which will allow the client to complete questions in private. Patients will be assured that they may stop the interview at any time without forfeiting the incentive and without penalty from the treatment facility. RTI staff collecting data will be able to assist patients in answering questions as needed. Patients will be given contact information for the study's principal investigator and the study's IRB (Quorum) should they have any questions or concerns with the study.

Treatment facility staff participating in the Staff Focus Group will receive an informed consent form to complete prior to the Focus Group (Att. 13).

A.12 Estimates of Annualized Burden Hours and Costs to Respondents

A.12.1 Estimated Annualized Burden Hours

For patients, burden estimates are based on real-world implementation of the data collection tools and questionnaires of similar length, topic, and respondents. Specifically, similar versions of the Patient Check-In and Patient Questionnaires have been completed with 500 OUD patients in a private project conducted by RTI. The Patient Check-In Questionnaire takes about 10 to 20 minutes with average response time of 15 minutes. The Baseline Patient Questionnaire baseline takes 45 to 60 minutes with an average response time of 52 minutes including time to

review the consent forms. Similarly, the Patient Questionnaires at 12- and 24- month follow-up take 40 to 50 minutes to complete with an average of 45 minutes. The Patient Screener Form is designed to quickly obtain basic information about the client and is estimated to take 5 minutes to complete. These estimates are based on experience with similar tools and client populations. Patient and Staff Focus Groups will be limited to 90 minutes including time to review consent forms.

Exhibit 5 reports the average number of respondents per year over the 3 years of data collection and requested OMB approval. Four thousand seven hundred thirty-two patients are expected for the Patient Screener Form in the first year; averaging these respondents over 3 years yields an average of 1,577 respondents per year, each completing the form once. The Client Check In is expected to be completed by 2,848 respondents and when annualized (dividing by 3 years) yields 949 patients per year completing the questionnaire twice. Annualized Patient Questionnaire Baseline respondents is based on 3,560 patients at baseline which annualizes to 1,187 patients per year completing the questionnaire once. For the Patient Questionnaire 12-month follow-up we expect 2,791 respondents which annualizes to 930 patients per year (2,791/3); similarly, for the Patient Questionnaire 24-month follow-up we expect 2,233 respondents which annualizes to 744 patients per year (2,233/3). Finally, 27 participants per year, from each type of respondent (patients and facility staff) will participate in Focus Groups.

Exhibit 5. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (hours)	Total Burden (hours)
Patients	Client Screener (Att. 4)	1,577	1	1,577	5/60	131
	Client Check-In (Att. 5)	949	2	1,898	15/60	474
	Client Questionnaire Baseline (Att. 6)	1,187	1	1,187	52/60	1,029
	Client Questionnaire 12-Month Follow-up (Att. 6)	930	1	930	45/60	698
	Client Questionnaire 24-Month Follow-up (Att. 6)	744	1	744	45/60	558
	Client Focus Groups	27	1	27	90/60	41

	(Att. 7)					
Treatment facility staff[+]	Focus Groups (Att. 8)	27	1	27	90/60	41
Totals	**--**	**3,270[*]**	**--**	**6,390**	**--**	**2,972**

[+] Treatment facility staff includes administrators, clinicians, doctors, nurses, and counselors.
*Number of respondent total is the average unduplicated number of respondents per year. For patients, 4,732 are expected to respond in year 1, 2,818 in year 2, and 2,260 in year 3. Each year, 27 treatment facility staff are also expected to respond. On average, 3,270 respondents are expected each year. Our calculations are as follows: [(4,732+2,818+2,260) + (27x3)]/3 = 3,270 respondents per year.

A.12.2 Estimated Annualized Cost to Respondents

Costs are estimated using Bureau of Labor Statistics mean hourly wages for substance abuse and mental health counselors, physicians and social service managers and the federal minimum wage. These hourly wages are presented in ***Exhibit 6***, along with the annualized costs to respondents.

Exhibit 6. Estimated Annualized Cost to Respondents

Respondent	Instrument	Total Burden Hours	Average Hourly Wage**	Total Respondent Cost ($)
Patient	Patient Screener	132	$7.25	$956
	Patient Check-In	594	$7.25	$4,307
	Patient Questionnaire, Baseline	1,02	$7.25	$7,460
	Patient Questionnaire, 12-month follow-up	698	$7.25	$5,061
	Patient Questionnaire, 24-month follow-up	558	$7.25	$4,046
	Focus Groups	41	$7.25	$297
Treatment facility staff[+]	Focus Groups	41	$ 51.26	$ 2,102
Total		**3,093**		**$ 24,225**

[+]Treatment facility staff includes administrators, clinicians, doctors, nurses and counselors. ** Wages are obtained from national Bureau of Labor Statistics (BLS) hourly mean wages for the types of treatment facility staff involved including Substance Abuse and Behavioral Disorder Counselors, Registered Nurses, Family and General Practitioners and Medical and Health Services Managers. Client respondent hourly wages uses the current Federal minimum wage.

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

The requested data collection does not impose a financial burden on respondents, nor will respondents incur any expense other than the time spent completing the surveys.

A.14 Annualized Cost to the Federal Government

Exhibit 7 presents the two types of costs to the government that will be incurred: (1) external contracted data collection and analyses and (2) labor for government personnel. The project is being conducted under a 4.5-year contract, with 3 years of data collection that was awarded on September 26, 2016. The annualized cost for the data collection task for the data contractor, including contractual payments to treatment facilities, is estimated at up to $1,940,535.

The government costs include personnel costs for federal staff involved in project oversight and development of this Information Collection Request; these efforts involve approximately 10% of a GS-14 Step 10 ($66.27 hourly rate) public health analyst, 10% of a GS-13 Step 5 ($48.89 hourly rate) program analyst, 10% of a GS-13 Step 1 ($43.14) and 20% of a GS 12's step 1 ($36.27 hourly rate). The total annualized cost to the federal government for federal staff for the duration of this data collection is $42,244.

Exhibit 7. Estimated Annualized Federal Government Cost Distribution

Type of Government Cost	Annualized Cost
Data Contractor	$1,940,535
Federal Staff	
GS-14 public health analyst at 10% FTE	$12,127
GS-13 program analyst at 10% FTE	$8,947
GS-13 program analyst at 10% FTE	$7,895
GS-12 contractors at 20% FTE	$13,275
Total	$1,982,779

FTE = full time equivalent

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

CDC expects an assortment of reporting and dissemination deliverables under the MAT Study fixed-price contract. These include contractually-required deliverables such as annual and final merged databases, annual site reports, and annual CDC reports. In addition, the contractor is expected to assist CDC with specified reporting needs that may arise, including short and long analytic reports, peer-reviewed journal articles, congressional briefings, annual evaluation reports, research and policy briefs, ad hoc analytic reports, best practices summaries, user guides, data and analysis documentation, and conferences or other presentations. All materials prepared for dissemination will obtain CDC scientific and policy clearance before distribution.

The expected time schedule for project activities is presented in ***Exhibit 8***. All data collection activities are subject to OMB approval.

Exhibit 8. Estimated Time Schedule for Project Activities

Activity	Expected Timeline
Treatment facility sampling frame development	Spring–Summer 2017
OMB approval	December 2017
Treatment facility and client enrollment	December 2017–October 2018
Ongoing treatment facility and client data collection	December 2017–October 2020
Data cleaning, preparation and analysis	January 2018–November 2020
Reporting and dissemination	January 2018–March 2021

OMB = Office of Management and Budget

A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate

No request for an exemption from displaying the expiration date for OMB approval is being sought.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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