Office of Management and Budget

Section A
Supporting Statement
for the
Case Studies in Patient-Centered Care Collaboration to Improve Minority Health

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Prepared for:
Office of Minority Health
U.S. Department of Health and Human Services
The Tower Building
1101 Wooton Parkway, Suite 600
Rockville, MD 20852

Prepared by:
Westat
1650 Research Boulevard
Rockville, MD 20850

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The U.S. Department of Health and Human Services (HHS), Office of Minority Health (OMH) is requesting approval from the Office of Management and Budget (OMB) for new data collection activities for the Patient Centered Care Collaboration to Improve Minority Health initiative (PCCC). The overarching goal of the PCCC Initiative is to explore how evidence-based comparative effectiveness research (CER) findings, also referred to as evidence based CER findings, can be translated and disseminated among minority serving health providers and racial and ethnic minority patients with diabetes, hypertension, and weight management issues. The intent of this effort is to help facilitate and inform future adoption of CER informed evidence-based practices by providers, patients and communities, using a case study methodology. Evidence based CER findings selected for this effort were identified through a comprehensive environmental scan conducted at the onset of the PCCC Initiative by Westat and subsequently vetted by various stakeholders, including community representatives in Chicago, Illinois and Houston, Texas.

Community-based stakeholders include the co-investigators and project staff at the academic institutions in Chicago and in Houston, which host and provide leadership at the local level for PCCC activities. Stakeholder presence is also embodied by representatives from partnering organizations where pilot testing of CER informed evidence-based practices will occur. These community representatives are from organizations and health systems that share an interest in disseminating and promoting the adoption of evidence based CER among the populations targeted. Collectively, these stakeholders form local hubs in the

project's two anchor cities—Chicago and Houston. Each local hub provides the infrastructure for coordinating local PCCC activities, including consensus building activities of their workgroups. A prominent component of the PCCC initiative is the project's Steering Committee comprised of multidisciplinary health professionals and researchers. This committee provides advice, technical expertise and scientific guidance on all study activities.

The early-on vetting process, mentioned above, helped to inform stakeholder engagement activities and facilitated assessment of the appropriateness of the CER findings for addressing the priority needs of the local communities in Chicago and Houston. In this connection, the designated CER findings reflect the interventions and strategies (also referred to as practices) that were translated or adapted for use with racial and ethnic minorities in community settings. Translation of the CER findings encompassed a range of activities such as recruitment of staff that were racially, ethnically, and/or linguistically representative of the target communities, cultural tailoring of informational products and tools to include cultural references (e.g., images, photos, cultural contexts, etc.), and development of patient/consumer oriented materials developed at the 5th grade reading level. Accordingly, these adaptations to the CER findings serve as the foundation for the CER evidence-based practices identified for dissemination in the two local community-based programs.

The program in Chicago is the Health Empowerment Lifestyle Program (HELP). The nexus of the Houston effort is the MyRx Medication Adherence Program. The data collection activities in Chicago and Houston will provide insight into the facilitators, criteria, and processes for disseminating and implementing culturally adapted, CER informed evidence-based practices in racial and ethnic minority communities in which social and demographic factors have been found to negatively influence health and wellbeing.

The PCCC study's inherent data collection process is necessary because health outcomes of racial and ethnic minorities are influenced by multiple social determinants such as accessibility of health services and information, language and cultural barriers, availability of a support system, and neighborhood context. Granted, evidence based CER has been identified, reported on, and summarized in the literature. However, there is a dearth of information on how CER strategies

can be translated and disseminated to meet the cultural and linguistic needs of vulnerable racial and ethnic groups in the specific community settings where they reside and receive care. Similarly, information is limited about translation and dissemination of evidence based CER findings to promote their adoption by minority serving providers. Consequently, a greater understanding and awareness is needed to determine the most useful approaches for translating and disseminating evidence based CER while taking into account critical socio-demographic factors.

It is important to note that the PCCC data collection will not address the effectiveness of the already evidence based CER. Rather, it will focus on understanding how to translate, disseminate and promote the adoption of these findings in real world, community settings. Research informs us that context and place are important in health care delivery. Therefore, ethnicity and community are paramount components in this process and the PCCC Initiative is vital towards this end.

Also, determining the extent to which the programs produce any observed changes in participants' behaviors or improvements in their health status is similarly beyond the scope of this data collection effort. This collection will explore the reactions and perceptions of participants, providers, and community stakeholders to the CER informed evidence-based practices as implemented in their communities. Patient and consumer participants will be given clinical feedback regarding changes in their biological markers. Data collection activities involving all participants (i.e., patients, consumers, implementation staff, facility administrators, and Steering Committee members) will be used to determine if improvements need to be made in the translation and in dissemination strategies.

Administrative Requirements of the Collection. The 2009 American Recovery and Reinvestment Act (111th Congress, H.R.1 American Recovery and Reinvestment Act of 2009) allocated $400,000,000 to the HHS Secretary with the provision that these appropriations be used to accelerate development and dissemination of research designed to assess the comparative effectiveness of health care treatments and strategies. This legislation further emphasized that the Secretary should consider recommendations of the Federal Coordinating Council for Comparative Effectiveness Research and those compiled in an

Institute of Medicine Report of national priorities for Comparative Effectiveness Research. The OHM-PCCC Initiative is in accordance with this national legislative charge. The PCCC serves to explore, and understand, the translation, dissemination, and adoption of activities called for by the Federal Coordinating Council on Comparative Effectiveness Research. An additional provision in the legislation was to ensure that activities conducted with this funding are consistent with HHS' policy related to inclusion of women and minorities in research.

The launch of the OMH PCCC Initiative was in response to guidelines developed by the Office of the Assistant Secretary for Program Evaluation (ASPE) and the Agency for Healthcare Research and Quality (AHRQ), which asked for proposals on dissemination and adoption of CER. It is our understanding that this OMH PCCC is the only initiative funded to promote dissemination and adoption of evidence based CER in racial and ethnic minority populations. While other funded initiatives may include racial and ethnic minorities, PCCC is designed to engage community stakeholders in tailoring evidence based CER to the needs of these populations. PCCC is also unique in that the study focuses on what can be learned about strategies that translate and promote dissemination and adoption in these populations. Importantly, this study may provide the only opportunity under the current funding to examine the factors that influence and promote dissemination to minority groups.

2. Purpose and Use of Information Collection

The purpose of this data collection request is to acquire information to better understand what translation is needed to facilitate dissemination and adoption of evidence based CER practices among racial and ethnic minorities in health care and community settings, in selected geographic areas. As noted in the previous section, one of our aimss was to ensure their appropriateness for use in "real world" settings and for use with racial and ethnic minorities to improve diabetes, hypertension, and weight management translation of the evidence based CER occurred during an earlier phase of the PCCC Initiative. Adaptations were made to address the cultural and linguistic needs of racial and ethnic minorities. The

population groups to whom the PCCC efforts are targeted include African Americans, Hispanics/Latinos, and Asian Americans in Chicago, Illinois and Houston, Texas. Towards this end, we have worked, and will continue to work, closely with community partners and stakeholders on achievement of the following categorical objectives. These objectives are commensurate with the interests of ASPE, AHRQ and the Federal Coordinating Council for Comparative Effectiveness Research as they endeavor to learn how best to move evidence based CER findings from research to practice.

Study Objectives:

1. Translate and Disseminate Evidence-Based Practices
2. Implement Evidence-Based Practices in Chicago and Houston
3. Facilitate Adoption of Evidence-Based Practices
4. Describe the characteristics of stakeholders who were instrumental in the PCCC Initiative and in HELP/MyRx
5. Describe the overall engagement and involvement of stakeholders and participants in the CER Based HELP/MyRx

An overarching aim of the study is to discern answers to the following five questions which are correlates of the PCCC research objectives and represent the foundation and focus of the data collection activity. We intend to use a case study methodology to achieve these objectives. For illustrative purposes, a table that maps initiative activities and research methods to the following objectives are provided (Attachment 1).

Study Objectives/Correlate Queries:

1. What are the criteria needed to translate evidence-based practices for the dissemination of programs serving racial and ethnic minority populations in community settings?
2. What are the successes and challenges associated with the implementation of HELP in Chicago and MyRx Medication Adherence in Houston?

3. What are some of the factors that facilitate the adoption of evidence-based practices in racial and ethnic minority populations and community settings?

4. Which stakeholders were instrumental in translating and disseminating the evidence based CER (e.g., demographics, health conditions, medications, knowledge base of participants and providers) and which facilities were instrumental in disseminating and implementing the evidence based CER?

5. What factors contributed to the stakeholders' overall involvement and engagement with HELP in Chicago/MyRx in Houston (participants, implementation staff/providers, community stakeholders, and facility administrators)?

Data to respond to each of the objectives will come from five groups at each site as follows:

- **Participants**—Includes all persons who meet the eligibility criteria and enroll in the program. Each program has a specified set of inclusion and exclusion criteria for participants (see Attachments 2 and 4 for these specifications). At a minimum, the participants must meet the race/ethnicity and health conditions identified for this project.

- **Implementation Staff**—These are the Community Health Workers and Health Educators staff who will deliver HELP in Chicago and the Pharmacists and Health Educators who will deliver MyRx in Houston. Each staff will be recruited and selected based on a set of criteria described in Part B. At a minimum each staff will have experience delivering similar programs and working with similar target populations.

- **Facility Administrators**—In Chicago, these administrators are the clinic administrator and primary physician who works with the participating patients in the clinic. In Houston, these are the four facility managers of the residential buildings where participants are recruited and where the program will take place. Each administrator will be selected due to their involvement in the program and their role as administrator of the venue. In each case, this is a unique individual, no others hold the same role at the

facility.

- **Local Hub Members**—The local hub members are stakeholders, in each site location, who were selected to participate in a leadership role on this project. Each local hub provides the infrastructure for coordinating local PCCC activities, including consensus building activities of their workgroups. Stakeholders were selected based on their involvement in community activities, the organizations they represent, and their availability to serve.

- **Steering Committee Members**—This committee serves a leadership role for the PCCC initiative. It is comprised of multidisciplinary health professionals and researchers. This committee provides technical expertise and scientific guidance on all study activities. The committee members were selected based on their involvement and scholarly activities in health disparities in national and professional organizations, and academic institutions.

Brief descriptions of HELP and MyRx are provided below to offer a broader understanding of the purpose of the information collection. Each program will serve as a case study. See Attachments 2 and 4 for more details of each one.

OMH-PCCC IN CHICAGO

Health Empowerment Lifestyle Program (HELP): See Attachment 2 for more detail. HELP, based in Chicago, Illinois, is a spinoff of the Diabetes Empowerment Education Program (DEEP). This effort focuses on diabetes and hypertension self-management and control, and weight management. HELP's learning objectives are to: 1) identify risk factors and ways to prevent them; 2) understand the disease and its impact on the body; 3) know the numbers associated with the disease (e.g., HbA1C, blood pressure, and weight); and 4) understand the benefits of monitoring and managing diet, physical activity, and medication, and the cultural differences associated with diabetes, hypertension, and obesity.

CER strategies utilized in HELP include:

- Telephone reminders/booster follow-ups regarding activities
- Use of ethnic based physical activities
- Use of community health workers (CHW) to train and recruit patients. These professionals will be of the same cultural background as the participants and will speak their language.

HELP is a 12- week program that includes 2 sessions for data collection. There are four concurrent cycles of group educational sessions. Each class size will consist of no more than 25 patients per class, which will be convened weekly. The classes will be interactive 2-hour long sessions. Telephone reinforcement/follow-up calls will be conducted weekly, and classes will be offered in English or Spanish. Some of the culturally appropriate strategies identified and incorporated into HELP include:

- Use of peer educators such as bilingual Latinos and African American CHWs (We believe that educators need to be of the same ethnic/racial group as participants).
- Health literacy and culturally-appropriate educational curriculum (added a weight management/obesity module to the curriculum and included content on hypertension). Efforts were made to incorporate pictures (art work, and simple terms) so both the CHWs and participants could understand the information.
- Group activities/exercises in each module to render the educational sessions more interactive, and participatory, and a lot more interesting as participants are learning by doing.
- Incorporation of reinforcement and support to participants. CHWs will make follow-up calls between classes to provide support and assistance to participants on any issue that they may be concerned about and to remind participants of the upcoming class. These will be tailored to the participants' specific health language and cultural needs.
- Translation of HELP into Spanish. This calls for translation of the program evaluation protocol, consent form and the new modules.

The PCCC Initiative's Chicago site will assess the translation and dissemination efforts of the evidence based CER through participant focus groups, implementation staff focus groups, facility key informant interviews, local hub member key informant interviews, and Steering Committee surveys. Specific queries will be made, as appropriate, about each of the evidence based CER strategies implemented to help discern, for example, the appropriateness of the CER adaptations for use in the participating community settings. Select queries have also been formulated to gather information on the dissemination strategies and to determine where participants obtained information about these programs. Participants will also be asked about their preferred method(s) for obtaining information about their health. The data collection instruments are described here (see Attachment 3).

- **HELP Participant Screening Questionnaire (Attachment 3A)**—This questionnaire will be used to determine program eligibility.
- **Consent Form**—This document will inform the patient of the study; allow them to acknowledge their participation in the program; consent to complete program questionnaires; and have their clinical data HbA1c, blood pressure, weight, and height available to the program.
- **HELP Participant Intake Questionnaire**-Chronic Disease **(Attachment 3B)**—This questionnaire captures the baseline knowledge, attitude, and behavioral intentions data as well as HbA1c/blood sugar, blood pressure, weight, and waist circumference.
- **HELP Participant Post Questionnaire (Attachment 3C)**—This questionnaire captures the post-intervention knowledge, attitude, and behavioral intentions data; and HbA1c/blood sugar, blood pressure, weight, and waist circumference.
  A total of __focus groups will be held with XX participants.
- **HELP Participant Focus Group Guide & Questions** (Post-Intervention) **(Attachment 3D)**—Four focus groups will be held with up to 40 participants. Two groups will be conducted in English for African American participants. Two groups will be conducted for Hispanic/Latino participants, one will be conducted in Spanish and the other in English. These focus groups will allow participants to discuss and share their experiences with the program as well as offer

suggestions for improvements in program implementation related to translation and dissemination of CER strategies.

We will gather additional information from the PCCC implementation staff, the facility administrators, and the local hub members who have participated in this project.

- **HELP Implementation Staff: Community Health Worker, Health Educator Focus Group Guide & Questions (Attachment 3E)**—The focus group items will capture information about the providers (CHWs and health educators), and their experiences with the program. Items will also collect perceptions about the program in regards to translation needed prior to implementation, dissemination strategies, and implementation barriers and successes. The staff will be required to complete a brief profile as part of their focus group participation to help understand their characteristics. One focus group will be conducted for these staff.

- **Facility Administrator Key Informant Interview Questions (Attachment 3F)**—These items are designed to capture information about the facilities (Chicago: health clinic) used as the program site for this project. This will include their role in the community, who they serve and their experience with the program. The key informant interviews will gather facility administrators' thoughts about the program in regards to site specific translation needs they addressed prior to implementing the program, as well as thoughts regarding dissemination strategies used, and implementation factors, successes, and challenges. Two interviews will be conducted, one with the clinic administrator and one with a clinical physician.

- **PCCC Chicago Local Hub Member Key Informant Interview Questions (Attachment 3G)**—These items will capture information about the local hub members and the organizations they represent. This information will allow us to understand their role on the project, how they viewed the project, and their involvement. The focus group will allow them to express their thoughts about the program in regards to what if any translation was needed prior to implementing the program, dissemination strategies used, and implementation factors, successes, and challenges.

OMH-PCCC IN HOUSTON

MyRx Medication Adherence Program: (See Attachment 4 for a more complete description). The focus of this program, anchored in Houston, Texas, is medication management for patients with hypertension and diabetes. The MyRx Medication Adherence Program is based on a Patient Centered Medical Home (PCMH) model where health and community professionals (hereafter referred to as PCCC staff) partner with patients to improve health outcomes. The professionals deployed in this study will be of the same cultural background as the participants and will speak their language. The learning objectives are to: teach patients medication management and self-management.

The program will be delivered by pharmacists (who will be trained by Harris County Hospital District health educators in motivational interviewing and cultural competency). The pharmaceutical care medication management approach includes a medication assessment, development of a care plan, and follow-up. Licensed pharmacists, who are from the same cultural group as the participants, make residential visits to patients in their senior residential building and provide telephone follow-ups. Health educators, with the support of pharmacists, provide educational sessions for seniors.

Evidence based CER strategies utilized in this intervention include: pharmacist home visits, group health education classes, and one-on-one provider driven follow-up telephone calls. The number of sessions planned or the dosage the participants will be exposed to include: 1) one hour home visit conducted by a pharmacist; 2) two monthly health education group classes for 60 minutes each at each facility taught by health educators; and 3) two reminder follow up calls involving pharmacist consultation with the participant within 2 weeks of each educational session.

The total study time is less than 5 hours over a 3-month period per participant. Sessions and materials have been tailored to the culture and language of participants. Data will be collected through in-person interviews, telephone interviews, and focus groups at four points. PCCC implementation staff will

collect baseline data in month 1. Pharmacists will conduct telephone follow-ups in months 1 and 2 and post-intervention data at the end of month 3 of a 3-month intervention program. Focus groups will be conducted after the last session.

Linguistic adaptations have been made for this program based on CER findings and community needs. Information will be provided at each educational session in a language appropriate format. A translator or a healthcare provider who speaks the dominant language at the facility will be utilized, as necessary. Additionally, pharmacists who speak the desired language will be utilized to conduct the telephone counseling. Relevant reading materials in the predominant languages of English, Spanish, and Chinese will be distributed at the educational classes according to the module that is being covered. Educational classes will also incorporate the use of material relevant to the various cultures (i.e., the use of culturally specific food pyramids in the nutrition module). Also, all healthcare providers who participate in the project will undergo cultural competency training.

Facility administrators where the program will take place have also been involved in the adaptations to meet the needs of their residents. Educational sessions will be scheduled in coordination with the facility managers to determine the best availability of the participants. Residents from each of the targeted facilities will be queried on an ongoing basis to address any concerns participants may have expressed.

In regards to the evidence based CER, the length and frequency of the classes were based on input from the facility managers and the facility residents and information from the CER scan. The workgroup decided on the frequency of the telephone consultations according to information from the CER scan and the resources available to reach the population.

We will assess the translation and dissemination efforts of the evidence based CER through the participant focus groups, implementation staff focus groups, facility key informant interviews, local hub member key informant interviews, and Steering Committee surveys. Specific queries will be made, as appropriate, about each of the evidence based CER strategies implemented to understand, for example, whether the adaptations made were appropriate for use with the

populations in the targeted community settings. Items were also developed to gather information on the dissemination strategies and to understand where participants obtained information about these programs and how they prefer to obtain information about their health.

The data collection instruments (see Attachment 5) are described below. Clinical data will be captured by the pharmacists who are trained to take blood pressure readings, measure diabetic HbA1c levels, and weigh patients. Since the patients are not directly linked to a health facility for this program, we will not obtain electronic medical records for the clinical data. Houston will use the following tools:

- **MyRx Participant Eligibility Screening Form (Attachment 5A)**—Hypertension and Diabetes screening form will be administered during recruitment phase by project staff. This questionnaire will be used to determine program eligibility. The consent form is included in this screening form.

- **MyRx Participant First Home Visit Form for Diabetes/Hypertension/Diabetes and Hypertension** (one form will be administered depending on the health status of the participant) **(Attachment 5B)**—The form that the pharmacist will use during the initial home visit will be guided by the patient's condition. This questionnaire will capture the baseline knowledge, attitude, and behavior/behavioral intentions data.

- **MyRx Participant Telephone Follow-Up: Being Active and Managing Stress** (month 1 only) **(Attachment 5C)**—The pharmacists will administer this following the first monthly educational session.

- **MyRx Participant Telephone Follow-Up: Healthy Eating** (month 2 only) **(Attachment 5D)**—The pharmacists will administer this following the second monthly educational session.

- **MyRx Participant Post-Intervention Follow-Up Form for Diabetes, MyRx Participant Post-Intervention Follow-Up Form for Hypertension, MyRx Participant Post-Intervention Follow-Up Form for Diabetes and Hypertension** (one form will be administered depending on the health status of the participant) **(Attachment 5E)**—

This data will be collected two weeks following the final follow-up call by the pharmacist. This questionnaire will capture the post-intervention knowledge, attitude, and behavioral intentions data as well as clinical indicators (HbA1c, blood pressure, weight, height). It will be administered by the Houston Hub staff.

- **MyRx Participant Focus Group Guide & Questions** (Post-Intervention) **(Attachment 5F)**—Four focus groups will be held with up to 30 participants, one group will be conducted in each of the four facilities. These focus groups will allow participants to discuss and share their experiences with the PCCC program as well as offer suggestions for improvements in program implementation related to translation and dissemination of CER strategies.

We will gather additional information for this project from the PCCC implementation staff, the facility administrators, and the local hub members who have participated in this project.

- **MyRx Implementation Staff: Pharmacist, Health Educators Focus Group Guide & Questions (Attachment 5G)**—The focus group items will capture information about the implementation staff (pharmacists and health educators), and their experiences with the program. The focus group will collect thoughts about the program in regards to translation needed prior to implementing the program, dissemination strategies, and implementation successes and challenges. The staff will complete a brief profile prior to participating in the focus group. Ten staff will participate in this focus group.

- **Facility Administrator Survey and Key Informant Interview (Attachment 5H)**—These items will capture information about the facilities (in Houston, the residential housing units) used as program sites for this project. This will include their role in the community, who they serve and their experience with the program. The key informant interviews will gather facility administrators' thoughts about the program in regards to site specific translation needs they addressed prior to implementing the program, as well as thoughts regarding dissemination strategies used, and implementation factors, successes, and challenges.

- **PCCC Houston Local Hub Member Key Informant Interview Questions (Attachment 5I)**—These items will capture information about the local hub members—co-investigators and project staff at the academic institutions that host and provide local leadership for the PCCC activities—and the organizations they represent. This information will allow us to understand their role on the project, how they viewed the project, and their involvement. The focus group will allow them to express their thoughts about the program in regards to what if any translation was needed prior to implementing the program, dissemination strategies used, and implementation factors, successes, and challenges.

- **Steering Committee Members Survey (Attachment 8)**—We will also gather additional information for this project from the PCCC steering committee members who have participated in project leadership. This survey will capture information about the steering committee members and the organizations they represent. This information will allow us to understand their role on the project, how they viewed the project, and their involvement. This information will allow them to express their thoughts about the program particularly in regards to leadership. Members will be selected based on their level of participation in the project. We can learn from those who were active participants as well as those who were unable to participate as they anticipated.

Use of Information. Study results will be used to develop guidance and tools to inform others of considerations and criteria relative to translating and disseminating CER informed evidence-based practices in different racial and ethnic groups and community settings. This guidance will be beneficial to others interested in adopting evidence-based practices for use in other African Americans, Hispanic/Latinos, and Asian health improvement programs that address diabetes, hypertension, and obesity.

Consequences of Not Collecting the Data. The funding for this study was intended to contribute to the body of evidence needed to disseminate and promote the adoption and use of CER. The data from this study will be valuable to researchers as well as practitioners in the field. Consequences of not collecting the data include: 1) knowledge gaps related to appropriate strategies for

translation, dissemination and implementation of culturally tailored CER-informed practices in minority communities will persist; 2) OMH will fall short of meeting its responsibilities for receiving ARRA funding to conduct this research; and 3) the Federal government will not be able to answer key questions related to the implementation of CER in different settings among various population groups.

It is our understanding that OMH PCCC is the only initiative funded specifically to promote dissemination and adoption of evidence based CER in racial and ethnic minority populations. While other funded initiatives may include racial and ethnic minorities, PCCC is specific to these populations and designed to engage community stakeholders in tailoring evidence based CER to the needs of these populations. PCCC is also unique in that the study focuses on what can be learned about strategies that promote dissemination and adoption in these populations. Importantly, this study may provide the only opportunity under the current funding to examine the factors that influence and promote dissemination to minority groups.

3. Use of Improved Information Technology and Burden Reduction

In Chicago, the patient's clinical information (HbA1c, blood pressure, and weight) will be retrieved from their electronic medical records (EMR) at the participating health clinic by clinic staff. This data will initially be used to determine eligibility for HELP/MyRx. Obtaining information from the EMR will reduce the burden for staff in retrieving the patients' clinical data.

In Houston, these data elements are not available electronically. The patient's clinical information will be obtained by the pharmacist during the home visit since there is no direct link to the patient's medical record, electronic or paper.

We understand that the information collected using the survey instruments, focus groups and interview are not available electronically. Therefore, we will collect it through paper and pencil forms, and focus group and interview

discussion summaries. The Chicago and Houston programs will collect the participant information on knowledge, attitudes, behavioral intentions, and use of evidence-based practices using paper and pencil forms. Any new staff will be trained on data collection procedures.

4. Effort to Identify Duplication and Use of Similar Information

The literature review conducted for this project did not identify any studies that were identical to this one. There is no duplication or other similar information available for this project, therefore, no data are available to respond to the evaluation questions posed for this project. The evidence based CER included in these programs have not previously been implemented in Chicago or Houston as they are specifically defined for this project.

5. Impact on Small Businesses or Other Small Entities

This data collection activity does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

We propose to collect data at two time points for the Chicago program and four time points for the Houston program. The Chicago program will collect data at baseline and post-intervention. The post intervention collection will include conducting the participant, implementation staff, and facility administrator surveys, focus groups, or key informant interviews. These times are routine data collection points for most intervention programs. Data will be collected at week 1 and week 12.

The Houston program will collect data at baseline, two "booster" telephone follow-ups, and post-intervention (the post intervention collection will include conducting the participant surveys and focus groups, implementation staff focus groups, facility administrator and local hub member key informant interviews). These are typical data collection points for evaluations of intervention programs that have booster/telephone follow-ups as a part of the intervention. For patient specific information, we will only look at pre and post differences, for example, biological markers such as HbA1c, to inform patients of progress made while in the program.

A minimum of two collection points is required to assess the extent to which translational activities achieved the anticipated influence in terms of delivery of culturally and linguistically tailored information. We will also need to assess whether the approach to disseminating the information was successful in achieving desired results. Collection of data at less than two points will not allow for an exploration of pre and post differences that are associated with participation in the program. We would not be able to assess the translation and dissemination approaches that are associated with participation in the program with only one data point. We also will need pre and post data to answer the study questions, determine fidelity, and assess the successes and challenges of program implementation from the perspectives of program participants.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation

The 60-day notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on September 23, 2011 (76 FR185: 59130-59131). The 30-day notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on December

15, 2011 (76 FR241: 78012). No comments were received in response to these notices. See Attachment 6 for a copy of the notices.

Outside consultation included members of the PCCC Steering Committee (see Attachment 7 for a list of members). These members represent researchers, academicians, health professionals and community stakeholders who have expertise working with racial and ethnic minority populations and expertise working to reduce health disparities. OMH also consulted with staff from the Office of the Assistant Secretary for Planning and Evaluation.

9. Explanation of any Payment/Gift to Respondents

Providing incentives to respondents is a customary practice in social sciences research. Incentives are an important tool for retaining participants in the program and gathering more than just baseline data (Castiglioni, Pforr, and Krieger, 2008). Based on their past experiences of implementing a program with a similar methodological approach and population, the Chicago hub site will provide two incentive payments to their patients. Participants will receive a $15 gift card as an incentive upon completion of the program at week 12 to support retention and collection of the post-program data. In addition, Chicago will provide a $15 incentive to participants who participate in the focus group. Given that transportation is often a barrier for these participants, they will also receive bus passes to attend the program. Based on experience working with the study population, the Houston site will provide a $15 gift card for a local store to participants who complete the post-intervention interview. They indicate that this incentive is needed to encourage the patients to complete the survey. Their experiences have indicated that the participants may not be sufficiently motivated to complete the post-intervention interview in the absence of an incentive. In addition, Houston will provide a $15 incentive to participants who participate in the focus group.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality is of critical importance to this project as is concern for the protection of participant's rights. When the patients enroll in the CER evidence based program and attend the first session, they will be given a description of the project, the program, the data collection activities, and will be asked to give their consent to participate at that time (see Attachments 3 for Chicago's & 5 for Houston's consent forms). This information will also let the patients know that their participation is voluntary and if they refuse to answer the survey questions, they can continue with the program; and that this study involves collection of clinical data.

Since data will be collected at multiple points, personal identifiers will be required to link this information to relevant study elements. Hence, in compliance with the Regulations for the Protection of Human Subjects, the data collection effort has been reviewed and approved by Westat's Institutional Review Board (IRB), and by the IRB's affiliated with the Chicago, Illinois (University of Illinois at Chicago) and Houston, Texas (Texas Southern University) sites.

The Health Educators/Community Health Workers (trainers and implementation staff in Chicago); and Pharmacists, health educators (trainers and implementation staff in Houston) will comply with the Privacy Act and take necessary steps to keep patient information private and secure. To help achieve this, all data collection tools will use a unique project identification number for each patient. The key for this identifier will only be available at the local project site and will be kept separate from the patient identification numbers. Data will be stored securely at each site and access will only be given to trained staff on an as required basis. OMH and its contractors will not receive identifiable patient records. Patient-level information will be aggregated to, at a minimum, the level of the local community site.

The local project sites and all potential respondents will be informed about the steps that will be taken in an effort to maintain confidentiality throughout data

collection (to the extent permitted by law). All data will be closely safeguarded, and no institutional or individual identifiers will be used in reports. Only aggregate data will be reported.

On an annual basis, Westat staff are required to complete training on data confidentiality and security, and issues associated with research involving human subjects. All staff are familiar with the requirements of maintaining confidentiality and the importance of this for patients.

11. Justification for Sensitive Questions

A limited number of sensitive items will be gathered through this data collection activity. The biological markers, which are routinely collected from people who participate in health programs include: systolic blood pressure, HbA1c, cholesterol, and weight. This data is important to collect to determine program eligibility and to share with participants as feedback on their participation in the program. Participants will want to know their measurements at baseline and after the program is completed. We will also gather information on race and ethnicity variables that are germane to this project. This information will be used to describe any differences that may be found in participants' reactions to the programs; if there are different perspectives on the importance of the cultural appropriateness of the programs; and to examine the health disparities of racial and ethnic minority groups.

This data may be considered sensitive but it is critical to the nature of this project. Collecting this information from participants will be voluntary. Sites will use informed consent forms as required and as viewed appropriate by their individual organizations (see Attachments 3 &5 for consent forms). Participant data are routinely collected and subject to the Federal Regulations on Human Subject Protection (45 CFR Part 46; OMB No. 0925-0404).

12. Estimates of Annualized Hour

Each local hub site (Chicago and Houston) will collect data from participants at baseline and post-intervention; and telephone follow-ups in Houston. In addition, they will also collect data from the staff who implemented the HELP/MyRx programs, the facility administrators where the programs are implemented, and the local hub members who participated in this initiative as stakeholders. The respondents, data collection instruments, number of respondents and number of responses, time (in hours) estimated to respond, and the estimated total hour burden are provided in Exhibit 1A. The hour estimates were derived based on the pilot testing of these data collection instruments and experience administering these types of instruments with these populations. The respondents, data collection instruments, the estimated total hour burden, hourly wage rate, and total respondent costs are provided in Exhibit 1B.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

There are no capital, startup, operation or maintenance costs.

14. Annualized Cost to Federal Government

The principal additional cost to the government for this project is the cost of a contract to collect the data from the various local hub sites and to conduct analyses and reports from the data collected.. The estimated annualized cost for the contract for the PCCC is $996,500 and the PCCC evaluation effort is approximately $165,000.

In addition, a portion of the costs are for personnel costs of several Federal employees involved in the oversight and analysis of information collection, amounting to an annualized cost of $28,876.80 for Federal labor. The total annualized cost for the assessment is therefore the sum of the annual contract

and the evaluation costs ($996,500) and the annual Federal labor cost ($28,876.80), or a total of $ 1,025,376.80.

Exhibit 1A. Estimated Annualized Burden Hours

Type of Respondent/Tool Name	Number of Respondents	Number Responses Per Respondent	Total Responses	Average Burden Hours Per Response	Total Burden Hours
CHICAGO					
Participants					
HELP Participant Screening Questionnaire & HELP Evaluation Consent (Attach 3A)	200	1	200	10/60	33
HELP Participant Intake Questionnaire (Attach 3B)	100	1	100	40/60	67
HELP Participant Post Questionnaire (Attach 3C)	100	1	100	40/60	67
HELP Participant Focus Group Guide & Questions (Attach 3D)	40	1	40	90/60	60
Implementation Staff					
HELP Implementation Staff: Community Health Worker, Health Educator Focus Group Guide & Questions (Attach 3E)	5	1	5	60/60	5
HELP Facility Administrator Key Informant Interview Questions (Attach 3F)	2	1	2	90/60	3
Local Hub Members					
PCCC Chicago Local Hub Member Key Informant Interview (Attach 3G)	12	1	12	60/60	12
Sub-total	459		459		247
HOUSTON					
Participants					
MyRx Participant Eligibility Screening Form: Hypertension and Diabetes (Attach 5A)	200	1	200	15/60	50
MyRx Participant First Home Visit Form: Diabetes or Hypertension or Hypertension and Diabetes (Attach 5B)	100	1	100	40/60	66
MyRx Participant Telephone Follow-Up: Being Active and	100	1	100	20/60	33

Type of Respondent/Tool Name	Number of Respondents	Number Responses Per Respondent	Total Responses	Average Burden Hours Per Response	Total Burden Hours
Managing Stress (Attach 5C)					
MyRx Participant Telephone Follow-Up: Healthy Eating (Attach 5D)	100	1	100	20/60	33
MyRx Participant Post Intervention: Diabetes or Hypertension or Hypertension and Diabetes (Attach 5E)	100	1	100	20/60	33

Exhibit 1A. Estimated Annualized Burden Hours (continued)

Type of Respondent/Tool Name	Number of Respondents	Number Responses Per Respondent	Total Responses	Average Burden Hours Per Response	Total Burden Hours
HOUSTON (continued)					
MyRx Participant Focus Group Guide & Questions (Attach 5F)	30	1	30	90/60	45
Provider					
MyRx Implementation Staff: Pharmacists, Health Educators Focus Group Guide & Questions (Attach 5G)	10	1	10	90/60	15
Facility Administrators					
MyRx Facility Administrator Key Informant Interview Questions (Attach 5H)	4	1	4	90/60	6
Local Hub Members					
PCCC Houston Local Hub Member Key Informant Interview (Attach 5I)	10	1	10	90/60	15
Sub-total	654		654		296
Steering Committee Members (Attach 8)	12	1	12	60/60	12
Grand Total	1,125		1,125		555

Exhibit 1B. Estimated Annualized Burden Costs

Type of Respondent/Tool Name	Total Burden Hours	Hourly Wage	Total Hour Cost/ Respondent[1,2]
CHICAGO			
Participants			
HELP Participant Screening Questionnaire (Attach 3A)	33	$15.95	$526
HELP Participant Intake Questionnaire (Attach 3B)	67	$15.95	$1,069
HELP Participant Post Questionnaire (Attach 3C)	67	$15.95	$1,069
HELP Participant Focus Group Guide & Questions (Attach 3D)	60	$15.95	$957

Type of Respondent/Tool Name	Total Burden Hours	Hourly Wage	Total Hour Cost/ Respondent[1,2]
Implementation Staff			
HELP Implementation Staff: Community Health Worker, Health Educator Focus Group Guide & Questions (Attach 3E)	5	$34.97	$175
HELP Facility Administrator Key Informant Interview Questions (Attach 3F)	3	$34.97	$105
Local Hub Members			
PCCC Chicago Local Hub Member Key Informant Interview (Attach 3G)	12	$34.97	$420
Sub-total	247		$4,321

Exhibit 1B. Estimated Annualized Burden Costs (continued)

Type of Respondent/Tool Name	Total Burden Hours	Hourly Wage	Total Hour Cost/ Respondent[1,2]
HOUSTON			
Participants			
MyRx Participant Eligibility Screening Form: Hypertension and Diabetes (Attach 5A)	50	$7.33	$367
MyRx Participant First Home Visit Form: Diabetes or Hypertension or Hypertension and Diabetes (Attach 5B)	66	$7.33	$484
MyRx Participant Telephone Follow-Up: Being Active and Managing Stress (Attach 5C)	33	$7.33	$242
MyRx Participant Telephone Follow-Up: Healthy Eating (Attach 5D)	33	$7.33	$242
MyRx Participant Post Intervention: Diabetes or Hypertension or Hypertension and Diabetes (Attach 5E)	33	$7.33	$242
MyRx Participant Focus Group Guide & Questions (Attach 5F)	45	$7.33	$330
Provider			
MyRx Implementation Staff: Pharmacists, Health Educators Focus Group Guide & Questions (Attach 5G)	15	$34.97	$525
Facility Administrators			
MyRx Facility Administrator Key Informant Interview Questions (Attach 5H)	6	$34.97	$210
Local Hub Members			
PCCC Houston Local Hub Member Key Informant Interview (Attach 5I)	15	$34.97	$525
Sub-total	296		$3,167
Steering Committee Members (Attach 8)	12	$51.64	$620
Grand Total	555		$8,108

NOTES:

[1] Adult estimate based on Bureau of Labor Statistics May 2009 National Occupational Employment and Wage Estimates United States, median hourly wage: http://www.bls.gov/oes/current/oes_nat.htm#00-0000

Elderly estimate based on food stamp eligibility: http://www.foodstampguide.org/gross-and-net-monthly-income-eligibility-standards/

15. Explanation for Program Changes or Adjustments

This is a new project.

16. Plans for Tabulation and Publication and Project Time Schedule

The general timeframe is as follows:

- The program implementation is scheduled to begin July 2012 and end in September 2012
- The baseline data collection is scheduled to begin July 2012

Data for the PCCC evaluation will be analyzed and used to describe translation and dissemination strategies that were conducted. The analysis of data and data tabulations are needed to report results of the study to various federal offices prior to the end of the contract, September 29, 2012. The results of data collection will also be used to generate a final report and to prepare two publications on the overall study and on the role of stakeholder engagement in CER. The report will satisfy reporting requirements for ARRA funding.

The PCCC dataset will consist of each element coded into the reporting categories to answer the evaluation questions. These data are at the participant level. The participant data will be aggregated by demographic characteristics of patients and health conditions.

Data from the focus groups and key informant interviews will be analyzed using qualitative techniques that will allow the identification of themes and common responses from the participants. This data will generate lessons learned, which may, in concert with other information supportrecommendations for translation, dissemination, and adoption of programs in other health and community settings. Some of the data will be qualitatively explored based on participant characteristics such as demographics and health conditions. Patterns may emerge and different perspectives may be evident regarding program implementation

based on race/ethnicity, age, gender, and specific health condition(s), and whether a participant has one or more conditions addressed by the program. As described in Attachment 1, the data will be used to inform OMH's understanding of the five lines of inquiry outlined in section A.2. The data tables will be shared with the organizations listed below. They will be advised that these are case studies and that the data do not support statistical comparision.

- **Health Care Providers and Health Systems Administrators** who are looking for practical strategies they can use with their patients. These professionals will be interested in learning efficient ways of promoting dissemination and adoption of evidence based CER in their own practices.
- **PCCC Partners and Stakeholders** who serve as committee members for this project. These professionals represent a diverse array of constituents. They will be instrumental in disseminating project findings in their own communities and among their colleagues. The spread from their dissemination efforts can be far reaching since they represent health clinics, housing authorities, national health professions associations, community based organizations, researchers, and academicians. Their hope is that the lessons learned from the implementation of OMH PCCC in Chicago and Houston will provide invaluable guidance on how to adopt and expand the initiative in other target communities and underserved populations.
- **Community Based Stakeholders and Organizations** whose focus is to improve the health status of their communities may wish to use to promote adoption and use among their constituents.
- **Federal Agencies: OMH, AHRQ, and ASPE** whose missions include providing expertise on how to improve health and reduce health disparities can use the findings from this study to provide technical assistance and guidance to other federal partners, their research partners, as well as national, state, and community partners.

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

The OMB number and expiration date will be displayed on all data collection instruments for which approval is being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This data collection does not require or request any exceptions to the Certification for Paperwork Reduction Act Submissions.

References

Castiglioni, L., Pforr, K., and Krieger, U. (2008). The Effect of Incentives on Response Rates and Panel Attrition: Results of a Controlled Experiment. *Survey Research Methods*, 2(3), 151-158.

McGonagle, K. A., Couper, M.P., and Schoeni, R.F. (2011). Keeping Track of Panel Members: An Experimental Test of a Between-Wave Contact Strategy. *Journal of Official Statistics,* 27(2), 319-338.

Attachments