Supporting Statement for AIDS Foundation of Chicago's Midwest HIV Prevention and Pregnancy Planning Initiative

A. Justification

1. Circumstances Making the Collection of Information Necessary

HHS/Office of the Assistant Secretary for Health (OASH) grants under section 1703(a) of the Public Health Service Act, as amended (42USC 300u-2(a)), which authorizes the Secretary to support grants for community health programs for new and innovative programs in health information and health promotion, preventative health services, and education in the appropriate use of health care: www.gpo.gov/fdsys/pkg/USCODE-2009-title42/html/USCODE-2009-title42-chap6A-subchapXV-sec300u-2.htm.

The AIDS Foundation of Chicago (AFC) received funding from OASH to develop and implement the Midwest HIV Prevention and Pregnancy Planning Initiative (MHPPPI). The program goal is to reduce HIV infections and increase pregnancy planning among women in high HIV prevalence communities in the Midwest through building providers' capacity to offer expanded HIV prevention and family planning options. AFC and its partners will assess the current landscape regarding provider and consumer knowledge, develop targeted and culturally appropriate trainings for providers, and provide expert consultation on the integration of HIV prevention and pregnancy planning into health care delivered to women. MHPPPI education and training efforts are estimated to reach approximately 1,900 providers.This project will focus on Midwest health and service providers who serve women living with and at risk of HIV in Iowa, Illinois, Indiana, Michigan, Minnesota, Missouri, Ohio and Wisconsin. It will particularly target those who serve communities of color because of the structural barriers that are associated with their elevated prevalence of HIV.

Published data concerning the knowledge, attitudes, and behaviors of Midwestern HIV care and reproductive health care providers' regarding pregnancy planning is limited. Assessing the landscape through surveying a sample of medical providers in the Midwest will enable AFC to develop description of what is current. This type of climate survey is well established in program development. In effort to increase impact and reduce redundancies it is necessary to understand what is currently happening with the target population. In addition, a climate survey will allow us to establish the counterfactual model, or what would happen without our program.

2. Purpose and Use of Information Collection

To effectively help further refine and develop the MHPPPI program's training course, AFC will use an evaluation framework that includes process monitoring, outcome evaluation, and dissemination. This application seeks the approval for: 1) a descriptive climate survey; and 2) a qualitative substudy consisting of informant interviews. Results from both studies will assist in program development and refinement, but will not be used to draw any conclusions about MHPPPI's program impact. The surveys are designed to generation descriptive information and inform program development; it is not the intent of the surveys to evaluate outcomes.

The program's training content will be informed by an initial climate survey of a sample of medical providers within the Midwest. The goal of the climate survey is to describe the current landscape of service integration in the medical setting (e.g., integrating pregnancy planning options into routine HIV care visits) among the evaluated sample population of providers. The content of the curriculum for the trainings is currently being developed (and will be further refined based on findings of the initial "climate survey". The trainings have not yet begun. The MHPPPI program consists entirely of the training program. Content is being generated based on current staff knowledge, partner expertise, and

external subject area experts (consultants). Survey results will contribute to the content of the curriculum.

A cross-sectional survey of medical providers will be conducted in year 1, we refer to this as the "Climate Survey". All medical providers in the sampling frame will be eligible to participate in the MHPPPI training course. The climate survey will be administered via a web-based platform called Qualtrics. Participants will be recruited by an enumerated list populated from funding sources and professional networks of partner agencies. MHPPPI does not maintain a list of members, however, we will enumerate a list populated by partner agency professional networks. Participating in the climate survey (in either wave) is not related to participating in the training. While there will likely be overlap between those who complete the survey and those who attend the training, eligibility for the survey is not contingent on participation in the training likewise eligibility for the training is not contingent on completing the survey. The total sample size sought is 300, however, responses to web surveys are historically low therefore we cannot be certain what our response rate will be in this convenience sample. This cross-sectional survey will be repeated in year 3 to assess any changes in the landscape. The second wave of the survey is included in the burden estimate and tabulation and is a part of this application. We deem this survey cross-sectional despite being administered at two time points, this is because the respondents may not be the same. We are not following providers over time, but trying to assess the landscape of services, attitudes and knowledge over time in the aggregate. Thus, each survey will allow us to describe, in a cross-sectional manner, the climate of a convenience sampled selection of Midwest providers that participate in waves 1 and 2 of the collection. The survey methodology was chosen to assess the landscape of reproductive health and pregnancy planning options for HIV+ women and women in high prevalence communities offered by medical providers. Our hypothesis is that our training program may shift the landscape and increase the overall competency of medical providers (HIV primary and reproductive health care), thus evaluating the differences and similarities between findings before and after the trainings are offered will allow for our team to assess any potential changes in the landscape as well as inform future programmatic efforts. Due to the convenience sampling methodology utilized to recruit respondents for waves 1 and 2 of this collection, the observed changes in respondent "climate" may be due to various factors (e.g., drug formulary, policy, HIV prevalence, etc.) outside of the MHPPPI training curriculum, and our results will thus be interpreted with in context of the study's significant limitations. Due to under- or over-representation of particular groups (sampling bias) that will be introduced as a result of the convenience sampling methodology utilized in each wave of the study and the non-longitudinal collection of data, this study's results will not be generalized to the broader population of providers encompassed within the entire MHPPPI network. The specific study limitations will be discussed in all communications and publications that are produced as a result of this collection.

The chief aim of this study is to add substantive descriptive information to the field to underscore the need as well as inform the content of the trainings for medical providers.

Public health policy impact: In July 2015, the White House released the *National HIV/AIDS Strategy for the United States: Updated to 2020*. The document serves as a critical guide for agencies at all levels of government as well as community stakeholders to achieve the National HIV/AIDS Strategy's (NHAS) goals of reducing new HIV infections; increasing access to care and improving health outcomes for

people living with HIV; and reducing HIV-related disparities and health equities. AFC and other organizations have conveyed to the Office of National AIDS Policy (ONAP) the importance of prioritizing the integration of reproductive health services into HIV care and ensuring that HIV, primary, and reproductive health care providers receive the necessary training and capacity building to enable such integration and offering of services to people living with and vulnerable to HIV. The NHAS makes clear that the important role community stakeholders play in the implementation of the NHAS and achieving the goals it has outlined. AFC's Midwest HIV Prevention and Pregnancy Planning Initiative is an active contributor to advancing the NHAS goals.

Two different provider types will be surveyed in the climate survey.

- HIV Primary Care Providers
  - Inclusion criteria – Anyone who provides primary HIV care to persons of reproductive age (15-49)
  - Exclusion criteria – Clinicians who only provide care in ambulatory settings, exclusive care to persons not of reproductive age
- Reproductive Health Care Providers
  - Inclusion criteria – Anyone who provides reproductive health care to HIV+ persons or HIV- persons with HIV+ partners
  - Exclusion criteria – Clinicians who do not serve any HIV+ persons or HIV- persons with HIV+ partners

A qualitative substudy will be conducted with patients. This substudy will help inform the development of the curriculum content for the trainings. AFC and its partner agencies have heard many stories from patients about their experiences with reproductive health options; the qualitative interviews will allow us to systematically document these stories. We will thematically code all data and disseminate results in peer-reviewed journals with open access.

We will enroll up to 20 patients in the qualitative sub study; we will stratify participants on the two eligibility criteria aiming to enroll equal numbers in each arm (10 HIV+ people of reproductive age; 10 HIV- people with HIV+ partners). Participants will be recruited via partner agencies and will be screened for eligibility by evaluation staff at AFC.

Patients will be eligible to participate if they:

1. Self-reported HIV- of reproductive age with HIV+ partner; self-reported HIV- of reproductive age living in a high prevalence community; AND
2. Attended at least 1 visit with a reproductive health provider in the past 12 months; OR
3. Self-reported HIV+ of reproductive age; AND
4. Attended at least 1 visit with a HIV primary care doctor in the past 12 months.

MHPPPI was initiated with the provision of grant funding from the Office of Assistant Secretary of Health. The project started October 1, 2014 and runs through September 30, 2017. Training provision has not yet begun and is slated to start in the first quarter of 2016.

3. <u>Use of Improved Information Technology and Burden Reduction</u>

The provider survey will be administered using secure web-based data collection software which is HIPAA compliant. Invitation to participate in the survey (i.e., recruitment) will be done electronically through email. We anticipate approximately 300 providers completing the survey which should take only ten to fifteen minutes to complete. Such use of technology will prevent any undue burden, participants will be able to skip any questions they do not want to answer and will be able to stop

participating at any point. Qualitative interviews with approximately 20 patients will be conducted in person by the evaluation team. Surveys will take approximately 45-60 minutes to complete.

4. Efforts to Identify Duplication and Use of Similar Information

AFC conducted a literature review using multiple keywords in both PubMed and Google Scholar. The results identified a number of publications that helped form the methods and content of our current climate survey, however, results also identified a gap in the literature in that no survey focused on the Midwest. An additional gap was identified as the lack of information about reproductive health providers and their experience, knowledge, and behaviors of providing expanded HIV prevention and family planning options to HIV-positive women or women in HIV serodiscordant relationships (i.e., one partner is HIV-positive and the other partner is HIV-negative). The project team also consulted each of the four local project partners, who have national experience, including our partner with extensive provider training experience, the Midwest AIDS Training and Education Center. To ensure we were absolutely thorough in determining whether or not our climate survey was necessary, we also contacted four external content area experts who confirmed that such information is not currently available. They unanimously support the data collection as it will substantially contribute to the literature and will document information that is currently only known anecdotally.

5. Impact on Small Businesses or Other Small Entities

The online survey will only take 10 to 15 minutes to complete minimizing the time individuals must dedicate to participation. All participants will be allowed to skip any questions that they do not want to answer and will be allowed to end participation at any point. We designed the survey to "front-load" the most important questions, thus if a provider can only spare two minutes we will still gather some data of use. The qualitative interviews will last approximately 45-60 minutes. Additionally, patients will determine whether they participate or not in the qualitative interviews.

6. Consequences of Collecting the Information Less Frequent Collection

The survey will be administered twice, but the respondents may differ from the first and second administration. The second round of the survey will be conducted in within the 3 year clearance period, thus an extension will not be filed. No contact information will be collected in this anonymous and confidential survey, thus we will not seek to follow respondents longitudinally but rather ask for one-time participation. There is no incentive for participating in the online climate survey, we will not collect any identifying information from participants. While there is an incentive for the informant interviews, these are conducted in person, therefore participants do not need to disclose any identifying information to receive their gift cared (e.g., they do not need to sign their name for the gift card).

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

There are no special circumstances related to the guidelines of 5 CFR 1320.5.

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

A 60-day Federal Register Notice was published in the *Federal Register* on Thursday, March 12, 2015, vol. 80, No. 48; pages 13011-13012 (see attachment Federal Register Volume 80_MHPPPI). There were no public comments.

No consultations with industry were conducted.

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9. Explanation of any Payment/Gift to Respondents

Patients who participate in the qualitative surveys will receive $25 gift cards as a token of appreciation for their participation. The qualitative interviews are not risky in nature and are non-experimental; participants will be allowed to skip any question they do not feel comfortable answering and will be assured confidentiality. There will be no undue influence as the evaluation team does not have a direct relationship with patients nor will patients receive or be denied medical treatment as a result of participation or non-participation (Grant 2004). It is unlikely that we will be able to recruit and enroll our target number without this incentive. Previous research has demonstrated that offering incentives can be useful for increasing participation rates and reduces sampling bias among individuals who are less likely to participate in research studies (e.g., lower SES, lower education, minority race) (Guyll, 2003; Lynn 2001; Sharp 2006).

In previous qualitative studies with the same population (HIV+ patients) similar incentives have been given, ranging from $20 -$30 per 1-2 hours of participation (Kempf, 2010; Golin, 2002; Klitzman, 2004; Christopoulos, 2015).

10. Assurance of Confidentiality Provided to Respondents

We are requesting a waiver of written consent for both the online survey and the qualitative interviews. We will not collect any identifying information from participants. While there is an incentive for the informant interviews, these are conducted in person, therefore participants do not need to disclose any identifying information to receive their gift cared (e.g., they do not need to sign their name for the giftcard).The institutional review board, Solutions IRB, has approved the project and has waiver of written consent (IRB approval letter included).

Before participants are allowed to begin the online survey, they will be prompted to complete a consent form informing them of the reason for the study and why they were selected, the duration of the study, the risks and benefits of participation, and contact information if they have any questions or comments about the survey. Participants will not be allowed to begin the survey until they have selected the 'YES' option, signifying their willingness to participate.

Qualitative participants will receive an information sheet explaining the program evaluation and what is expected of them during the interview, as well as contact information for the PI. No contact information from participants will be asked for or recorded. This information sheet functions as the informed consent and will not be signed.

11. Justification for Sensitive Questions

HIV-related questions and reproductive health questions (including pregnancy planning questions) may be considered sensitive to some participants. While providers in the climate survey are asked to report on their services to clients they will be able to skip any question they do not want to answer and continue the survey (i.e., no mandatory fields). Similarly, qualitative study participants will be reminded that they can skip any question they do not want to answer. If participants become upset or want to discontinue participation they can at any point. Clinicians are available for back up support and guidance should any participant become upset, however, we do not anticipate this to happen.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hour

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Screening for climate survey round 1	800	1	1/60	13.33
Climate Survey	300	1	15/60	75
Screening for climate survey round 2	800	1	1/60	13.33
Climate survey round 2	300	1	15/60	75
Patient Qualitative Interview	20	1	1	20
Screening for patient interview	25	1	5/60	2.08
Total	2245			198.74

12B. Estimated Annualized Burden Costs

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Physicians	88.33	$92.25	$8,184.44
Nurse Practitioners	88.33	$45.71	$4,037.56
Total			$12,222

13. <u>Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs</u>
Not applicable. There will be no other cost burdens to respondents or record keepers.

14. <u>Annualize Cost to Federal Government</u>

The surveys (climate survey time 1, climate survey time 2 and qualitative sub study) will be conducted and analyzed within two years. The overall cost is associated with labor required to conduct the following activities: monitor and assess data; review quarterly reports and other documentation and create reporting system; review survey results; establish monthly conference calls; conduct and report site visits to funded grantee; and ensure accurate data; and adherence to program guidelines.

Cost breakdown by major budget category:
Cost of the Proposed Survey Activity

Personnel Costs (federal employee) $29,500.00
Other costs (travel, conference call line, copying supplies, site visit) $7,850.00
Total $37,350.00

15. Explanation for Program Changes or Adjustments

This is new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data analysis will be conducted by Amy Johnson, who is an infectious disease epidemiologist and also the Director of Research and Evaluation at AFC.

Univariate analysis will describe the sample of the climate survey including frequency tables for categorical variables and displays of median and mean values for continuous variables. Bivariate analysis will be used to detect any associations between categorical variables using chi-square and ANOVA for continuous variables.

Log binomial regression will be used to estimate prevalence ratios (PRs) from this cross sectional study. The outcome under investigation is factors associated with routinely discussing family planning with patients (coded dichotomously yes/no). Log binomial models use the log link function to connect the dichotomous outcome to the linear predictor. The limitation to this model is it may fail to converge. If this is the case a Poisson regression with robust variance estimator can be used. Data will be analyzed using Stata V 15.0.

Despite limitations of a convenience sample, we hypothesize our results will contribute substantially to the literature, we seek to publish our results in a peer-reviewed journal with open-access. Limitations will be included in all publications, with attention to the limitations of a convenience sample, cross sectional data, online survey methodology, geographic distribution of respondents, and qualitative methods. We will include information about generalizability and interpreting results including potential threats of bias- both information and selection bias.

The qualitative study data will be coded by the evaluation team using a grounded theory approach. Through a series of open coding we will reach saturation by looking for instances within transcripts as well as probing within interviews. We seek to publish the results of the study to add to the literature on this topic.

Project time schedule:

The MHPPPI program was initiated with the provision of grant funding from the Office of Assistant Secretary of Health. The project started October 1, 2014 and runs through September 30, 2017. Training provision has not yet begun and is slated to start in the first quarter of 2016. The climate survey (round 1) will begin immediately upon receiving approval from the OMB. Results from the survey will help inform curriculum content.

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

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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References

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