

FY14

Indiana State
Department of Health

Maternal and Child
Health

[Improving the Quality of Smoking Cessation Services for Pregnant Women.]

Funding Opportunity Announcement for FY14

Table of Contents

Key Dates.....	3
Required Application Instructions	4
Executive Summary	4
Part 2. Full Text	6
Section I. Funding Opportunity Announcement Description	6
Section II. Award Information.....	13
Section III. Eligibility Information	13
Eligible Applicants.....	13
Section IV. Application and Submission Information.....	14
1. Letter of Intent	14
2. Research Plan Component	15
Appendix.....	18
Page Limitations	18
Format for Attachments	18
Submission Dates and Times	18
Funding Restrictions	19
Other Submission Requirements and Information.....	19
Section V. Application Review Information	20
Review and Selection Process	24
Anticipated Announcement and Award Dates.....	25
Section VI. Award Administration Information	25
1. Award Notices	25
3. Reporting.....	26
Section VII. Agency Contacts.....	30
Maternal and Child Health.....	30
Grants management contacts	30

Part 1. Overview Information

Participating Organization(s)	Indiana State Department of Health
Components of Participating Organizations	Maternal and Child Health
Funding Opportunity Announcement (FOA) Title	Improving the Quality of Smoking Cessation Services for Pregnant Women.
Funding Opportunity Announcement Type	New
Category of Funding Activity	Health
FOA Purpose	The purpose of this FOA is to assist applicants with the preparation of an application that aligns with this announcement. The intent is to solicit proposals for a study to assess the cost-benefit of a smoking cessation intervention that targets pregnant smokers. The intent is to evaluate a contingency management (CM) intervention on prenatal smoking cessation. The suggested approach is a randomized controlled trial to assess smoking abstinence at end of pregnancy and cost-benefit of CM on prenatal smoking cessation. A comparison of CM and the current standard of care should be examined to determine greater efficacy and cost-benefit. The results of this study will inform health care insurers and providers on the cost-benefit of providing a CM intervention for pregnant smokers.

Key Dates

Letter of Intent Due Date	April 15, 2013 5:00 PM
Application Due Date	May 3rd, by 5:00 PM.
Estimated Start Date	October 1, 2013

Expiration Date	September 30, 2015
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Required Application Instructions

To be considered for funding, applications must be received by the ISDH no later than **FRIDAY, May 3rd, 2013 at 5:00 p.m. EST.**

Applicants are **required** to submit applications electronically. For electronic submission:

Submit applications via email to Eden Bezy—MCH Substance Use Prevention Coordinator, at ebezy@isdh.in.gov

MAIL all supplemental materials that are unable to be sent via email to:

Indiana State Department of Health
Division of Maternal and Child Health
c/o Eden Bezy, MCH Substance Use Prevention Coordinator
2 N. Meridian St.
Indianapolis, IN 46204

Applicants must use the **Quality Improvement Project: RFP Application** document (please do not alter the format).

Application must include all required information in the checklist found in the **Quality Improvement Project: RFP Application.**

Applications that do not comply with these instructions may be delayed or not accepted for review.

Executive Summary

- **Purpose.** The purpose of the FOA is to assist applicants with the preparation of an application that aligns with this announcement. The intent of this FOA is to solicit proposals to evaluate the effect of a smoking cessation intervention called contingency management (CM) on prenatal smoking cessation and to evaluate and assess the cost benefit of a CM intervention. The suggested study design is randomized controlled trial to assess smoking abstinence at end of pregnancy and cost-benefit of CM on prenatal smoking cessation. A comparison of CM and the current standard of care should be examined to determine greater efficacy and cost benefit. The results of this study will inform health care insurers and providers on the cost-benefit of providing a CM intervention for pregnant smokers.

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- **Funds Available and Anticipated Number of Awards.** The Indiana State Department of Health intends to distribute one award with a range of \$150,000 up to \$325,000 for three years totaling a maximum of \$975,000. The applicant should indicate if matching funds will be available to contribute to the goals of the project.
 - **Budget and Project Period.** An applicant may request a project period of up to three (3) years. The estimated total funding (including both direct and indirect) is maximum \$325,000 for the first year (12 month budget period). The estimated total funding (direct and indirect) for the entire project period is \$975,000 maximum. The project period will run from 10/1/2013 to 09/29/2016.
 - **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
 - **Eligible Institutions/Organizations.** Indiana institutions/organizations listed in Section III, 1.A. are eligible to apply. Consideration will be given to applicants that collaborate or partner with organizations statewide.
 - **Eligible Project Directors/Principal Investigators (PDs/Pis).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support.
 - **Number of PDs/Pis.** Applications may include more than one PI; however, the first PI listed will be the “contact PI” for all correspondence.
 - **Number of Applications.** Eligible applicant institutions may submit more than one application.
 - **Application Type.** New.
 - **Special Date(s).** None.

Part 2. Full Text

Section I. Funding Opportunity Announcement Description

1. Background and Purpose

Nature of the Research Opportunity

The purpose of the FOA is to assist applicants with the preparation of an application that aligns with this announcement. The intent of this FOA is to solicit proposals to evaluate the effect of a smoking cessation intervention called contingency management (CM) on prenatal smoking cessation and to evaluate and assess the cost benefit of a CM intervention. The suggested study design is randomized controlled trial to assess smoking abstinence at end of pregnancy and cost-benefit of CM on prenatal smoking cessation. A comparison of CM and the current standard of care should be examined to determine greater efficacy and cost benefit. The results of this study will inform health care insurers and providers on the cost-benefit of providing a CM intervention for pregnant smokers.

Background

Although the overall prevalence of smoking in Indiana has decreased over the last decade, Indiana still suffers from an alarming rate (17.1%) of mothers who report smoking during pregnancy. This compares to a national average of approximately 12.8%. In many counties, the rate of smoking during pregnancy exceeds 30%. Medicaid-insured pregnant women, which accounts for over half of all deliveries in the State, have higher smoking rates than privately insured women. Prenatal smoking significantly increases the risk for many adverse pregnancy outcomes, including low-birth-weight deliveries, preterm births, Sudden Infant Death Syndrome (SIDS), and infant mortality.

The division of Maternal and Child Health is dedicated to decreasing the infant morbidity and mortality rates in the state of Indiana. Helping mothers quit tobacco will decrease the risk for serious adverse health outcomes for babies, and in turn decrease the disease burden of all Hoosier families.

Common interventions such as behavioral counseling have shown to be minimally effective, resulting in a 6% increase of smoking cessation rates compared to control groups. However, contingency management (CM) strategies, which utilize incentives to reinforce smoking cessation during pregnancy, have been associated with an estimated 24% increase in abstinence rates.

Before wide-scale promotion of CM strategies for prenatal smoking cessation, it is important to know if CM is a cost-savings approach to prenatal smoking cessation. If a CM intervention is found to be cost-saving, the intervention could be promoted to private and public insurance agencies (e.g., Medicaid), which may ultimately reduce costs associated with maternal and

infant health care. Moreover, implementation of a more efficient and successful intervention could lead to better maternal and infant health outcomes.

The purpose of this Request for Proposals (RFP) is to fund a research collaborative with an Indiana college or university for the evaluation of contingency management (CM) methods in prenatal smoking cessation programs within the state. Applicants may choose to examine the cost-effectiveness and efficacy of contingency management methods in current prenatal smoking cessation program(s) in Indiana, or to develop and examine new program(s) that utilize CM as a method for smoking cessation during pregnancy.

Purpose

The purpose of the FOA is to assist applicants with the preparation of an application that aligns with this announcement. The intent of this FOA is to solicit proposals to evaluate the effect of a smoking cessation intervention called contingency management (CM) on prenatal smoking cessation and to evaluate and assess the cost benefit of a CM intervention. The suggested study design is randomized controlled trial to assess smoking abstinence at end of pregnancy and cost-benefit of CM on prenatal smoking cessation. A comparison of CM and the current standard of care should be examined to determine greater efficacy and cost benefit. The results of this study will inform health care insurers and providers on the cost-benefit of providing a CM intervention for pregnant smokers.

Healthy People 2020 and other National strategic priorities - This research addresses “Healthy People 2020” priority area(s):

- a. Tobacco use, Objective TU-6, to increase smoking cessation during pregnancy, and
- b. Maternal, Infant, and Child Health, Objective MICH-11, to increase abstinence from alcohol, cigarettes and illicit drugs among pregnant women.

This research addresses the CDC Winnable Battle to reduce tobacco use. In addition, this research is aligned with the Division of Maternal and Child Health’s goal of lowering Indiana’s high infant mortality rate, and improving birth outcomes for Hoosier families.

Public Health Impact - Through this announcement, The Indiana State Department of Health intends to fund one project that will have the potential to yield high impact research results by reducing public health burden and improving population health on a large scale. Wider implementation of a highly effective smoking cessation intervention during pregnancy could result in better maternal and infant health outcomes and reduction in healthcare costs associated with pregnancy, delivery, and early infant care.

2. Approach

Research Goals and Objectives

The purpose of the FOA is to assist applicants with the preparation of an application that aligns with this announcement. The intent of this FOA is to solicit proposals to evaluate the

effect of a smoking cessation intervention called contingency management (CM) on prenatal smoking cessation and to evaluate and assess the cost benefit of a CM intervention. The suggested study design is randomized controlled trial to assess smoking abstinence at end of pregnancy and cost-benefit of CM on prenatal smoking cessation. A comparison of CM and the current standard of care should be examined to determine greater efficacy and cost benefit. The results of this study will inform health care insurers and providers on the cost-benefit of providing a CM intervention for pregnant smokers.

In order to assess the effectiveness and cost-benefit of CM interventions, an RCT is needed with measures of overall medical costs and health outcomes for the CM intervention versus standard of care (e.g., behavioral counseling). The cost-benefit analysis should consider overall medical costs involved in the RCT, including both the program intervention costs and the reimbursed medical costs accrued during pregnancy, delivery, and up to 3-months postpartum for the mother and the infant. Primary health outcomes of interest are smoking cessation rates at end of pregnancy comparing the CM intervention to the standard of care. Secondary health outcomes include infant gestational age, infant birth weight, length of stay in neonatal intensive care unit, mother and infant's overall length of hospital stay, and maternal complications during pregnancy (including hospitalizations), and mother's quit rate at 3 months post-delivery. The desired RCT would employ a CM intervention that assesses and compares abstinence of smoking at end of pregnancy and cost benefit of the intervention versus the standard of care.

Objective 1: To design a study that assesses and compares abstinence of smoking at end of pregnancy and cost-benefit of CM interventions and standard of care. Components pertaining to this objective include:

- Developing the research protocol and submitting the protocol for human subjects review and for OMB clearance as required.
- Developing a process evaluation of key milestones of the project.
- Working collaboratively with ISDH staff on the design, analyses, and dissemination of study results, including sharing de-identified data with ISDH for secondary analyses.
 - The suggested research design is an RCT to increase smoking cessation among pregnant women, comparing a CM intervention and standard of care (behavioral counseling).
 - It is recommended that the CM intervention be modeled on proven effective prenatal smoking CM interventions published in peer-reviewed journals, showing approximately a 24% or greater reduction in smoking cessation by end of pregnancy compared to behavioral counseling.
 - The estimated sample size must be large enough to detect a clinically-meaningful difference in the biochemically verified abstinence of smoking at the end of pregnancy comparing the CM intervention to the standard of care.
 - It is recommended that the RCT inclusion criteria should include, but are not limited to: continued smoking after learning of pregnancy status,

singleton pregnancies, enrollment in the study within 16 weeks of estimated gestational age, as well as no current known use of illicit drugs or heavy use of alcohol.

Objective 2: To implement the study and analyze data to assess all outcomes including cessation and medical costs, infant and maternal outcomes. Estimate the overall medical costs accrued during pregnancy and up to 3-months postpartum for prenatal smokers receiving CM interventions and those receiving standard of care, and to estimate cost-benefit ratios that compare intervention to the standard of care arm.

- Assess abstinence of smoking at each visit and at end of pregnancy for prenatal smokers receiving high and low intensity CM interventions and those receiving standard of care. Abstinence should be biochemically assessed based on recommended standards or tests for assessing cessation that have high sensitivity and specificity, particularly among pregnant women. Biochemical verification could include, for example, carbon monoxide testing and/or cotinine validation using urine analysis.
- Estimate the overall medical costs accrued during pregnancy and up to 3-months postpartum for prenatal smokers receiving CM interventions and those receiving standard of care.
 - Medical costs should include, but are not limited to: prenatal care costs, hospitalizations during pregnancy, delivery hospitalizations for the mother, and subsequent hospitalizations or medical costs occurred up to 3-months postpartum.
 - Cost-benefit ratios should be estimated that compare the CM intervention to the standard of care.
 - Intervention costs should include costs for implementing the CM interventions and providing for all costs above and beyond the standard of care.
- Assess and compare incidence of infant outcomes and health care service utilization during pregnancy, at delivery and up to 3 months of age for infants of women receiving the CM smoking cessation interventions and those receiving the standard of care.
 - Specify data sources or collection methods for data on infants: birth weight, gestational age, length of time in the neonatal intensive care unit, length of delivery hospitalization and re-hospitalization or medical care up to 3 months of age.
- Assess and compare incidence of maternal outcomes and health care service utilization during pregnancy, at delivery and up to 3 months postpartum for women receiving the CM smoking cessation interventions and those receiving the standard of care.
 - Specify data sources or collection methods for data on any hospitalizations during pregnancy, any medical complications during pregnancy, mother's length of delivery hospitalization and any re-hospitalizations or medical care up to 3 months postpartum. Medical

complications should include, but are not limited to, the following: pre-existing and gestational hypertension, maternal depression, maternal anxiety, placenta previa, premature rupture of membranes, placental abruption.

Objective 3: To disseminate results and study findings

Timeline - The general timeline for the project will consist of 3 phases over 3 years. Grantees will work closely with ISDH/MCH on all activities defined below.

Phase 1: Development (Months 1-6)

- Design the intervention components.
- Design the RCT study and data collection instruments to evaluate the interventions.
- Develop the research protocol for the RCT and submit the protocol for human subjects review.
- Establish a Data Safety and Monitoring Board.
- Follow the research protocols of the organization.

Phase 2: Intervention implementation (Months 7-28)

- Finalize intervention materials (by 9 months)
- Recruit and train staff to deliver the intervention and to conduct the evaluation study.
- Pilot test the intervention, revise design as needed.
- Enroll women into the study, conduct interventions and follow participants throughout pregnancy and through 3 months after delivery.
- Conduct quality assurance of intervention implementation and data collection.

Phase 3: Study findings, publications, and dissemination (Months 29-36)

- Complete study data collection (by 31 months).
- Analyze data to assess abstinence from smoking at delivery and cost-benefit of the intervention and submit completed research findings to peer-reviewed journals.
- Share de-identified data with ISDH staff for secondary analyses.

Target population - The target population is pregnant smokers ages 18-44 years. The study population must include economically disadvantaged women as defined by at least 25% of the pregnant smoking women attending the prenatal clinics from the sites be Medicaid-insured pregnant women who continued smoking during pregnancy. Enrolling at least 25% of economically disadvantaged pregnant smokers is important because nationally, pregnant smokers are more likely to be low income and less educated than nonsmokers. Thus, having enough women with this background will

allow for assessing whether this intervention is effective with pregnant smokers from a variety of backgrounds.

Collaboration/Partnerships - The applicant should consider developing partnerships with the tobacco control agencies and maternal and child health care agencies in the community where the study will take place, as well as local schools of public health

Evaluation/Performance measurement - The applicant is expected to develop a process evaluation of key milestones of the project.

Translation plan - The application should address how research findings will be disseminated to key stakeholders.

3. Reference List

Adams EK, Melvin CL, Raskind-Hood C, Joski PJ, Galactionova E. Infant delivery costs related to maternal smoking: an update. *Nicotine Tob Res.* 2011;13(8):627-37.

CDC. PRAMS and smoking. <http://www.cdc.gov/prams/TobaccoandPrams.htm>. Accessed September 6, 2012.

Dietz PM, England LJ, Shapiro-Mendoza CK, Tong VT, Farr SL, Callaghan WM. Infant morbidity and mortality attributable to prenatal smoking in the U.S. *Am J Prev Med.* 2010;39(1):45-52.

Heil SH, Higgins ST, Bernstein IM, Solomon LJ, Rogers RE, Thomas CS, Badger GJ, Lynch ME. Effects of voucher-based incentives on abstinence from cigarette smoking and fetal growth among pregnant women. *Addiction.* 2008 Jun;103(6):1009-18.

Higgins ST, Washio Y, Heil SH, Solomon LJ, Gaalema DE, Higgins TM, Bernstein IM. Financial incentives for smoking cessation among pregnant and newly postpartum women. *Prev Med.* 2011 Dec 27.

Higgins ST, Bernstein IM, Washio Y, Heil SH, Badger GJ, Skelly JM, Higgins TM, Solomon LJ. Effects of smoking cessation with voucher-based contingency management on birth outcomes. *Addiction.* 2010 Nov;105(11):2023-30

Lumley J, Chamberlain C, Dowswell T, Oliver S, Oakley L, Watson L Interventions for promoting smoking cessation during pregnancy. *Cochrane Database Syst Rev.* 2009 Jul 8;(3):CD001055. Review.

SRNT Subcommittee on Biochemical Verification. Biochemical verification of tobacco use and cessation. *Nicotine Tob Res.* 2002 May;4(2):149-59.

Tong VT, Jones JR, Dietz PM, D'Angelo D, Bombard JM; Centers for Disease Control and Prevention (CDC). Trends in smoking before, during, and after pregnancy - Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 31 sites, 2000-2005. MMWR Surveill Summ. 2009 May 29;58(4):1-29.

Section II. Award Information

Application Types Allowed	<u>New</u> - An application that is submitted for funding for the first time.
Funds Available and Anticipated Number of Awards	<p>Indiana State Department of Health intends to commit up to \$325,000 in FY2014 to fund one applicant for the first 12 month budget period.</p> <p>An applicant may request a project period of up to three years. The funding amount may be up to \$325,000 each year for the 2nd and 3rd years of the project.</p>
Ceiling and Floor of Individual Award Range	<p>An applicant may request up to \$325,000 for the first 12-month budget period including both direct and indirect costs.</p> <p>The floor (minimum amount to be awarded) for this award is \$150,000 annually, \$450,000 over the total project period.</p>
Project Period Length	<p>The total project period for applications submitted in response to this FOA may not exceed three (3) years.</p> <p>Throughout the project period, ISDH's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and ISDH's determination that continued funding is in the best interest of the State government.</p>

Section III. Eligibility Information

Eligible Applicants

Eligible Organizations

Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Special Eligibility Requirements

Eligible applicants must have evidence of an established relationship with one or more study sites that meet the criteria:

- a. Must provide evidence, in the form of reports, letters or written agreements with study sites that report the number and percentage of pregnant smokers attending prenatal health services annually from each site where women will be recruited and enrolled into the study. The study population must include economically disadvantaged women as defined by at least 25% of the pregnant smoking women attending the prenatal clinics from the sites be Medicaid-insured pregnant women who continued smoking during pregnancy. Each clinic where subjects are recruited must have a smoking rate of at least 10% among pregnant women.
- b. Must provide evidence, in the form of a letter, of having access to and the ability to collect reimbursed medical costs for all related services. Must provide evidence of permission to access the medical cost data and how this data will be collected.
- c. Must provide evidence that the research team includes an economist with experience in cost-benefit research of interest. Must provide evidence of publications, references, and abstracts of relevant publications by the economist addressing the cost-benefit of an intervention.

Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for ISDH support.

Cost Sharing

This FOA does not require cost sharing, but applicants are encouraged to share with ISDH if their agencies are able to match any funds to aid in research efforts.

Number of Applications

Multiple applicants from an institution are invited to apply for this funding.

Section IV. Application and Submission Information

1. Letter of Intent

Those organizations planning to apply for this FOA are strongly encouraged to submit a letter of intent to Eden Bezy at ebezy@isdh.in.gov no later than 5:00 PM EST on April 15th, 2013.

The letter of intent should provide a brief overview of the expected project. Note that applicants will not be held to the exact project proposed in a letter of intent. It is understood and expected that final project proposals will be refined and may vary slightly from the letter of intent.

The letter of intent must include the following:

- Agency Name
- Collaborating Partners
- Targeted Counties
- Brief description of the target population
- Brief description of the Agency(s) where evaluation will be implemented

Letters of intent will be reviewed by the Indiana State Department of Health (ISDH) Maternal and Child Health (MCH) Division. Electronic feedback on partnerships, project ideas and performance measures may be provided by ISDH's Division of Maternal and Child Health to applicants who submit letters of intent, as deemed necessary.

2. Research Plan Component

As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application—provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
2. Specific Aims—state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. Research Strategy --the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

Human Subjects Section

4. Protection of Human Subjects
5. Inclusion of Women and Minorities
6. Targeted/Planned Enrollment Table (for New Application ONLY)
7. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan

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13. Consortium/Contractual Arrangements
 14. Letters of Support
 15. Resource Sharing Plan(s)
 16. Appendix

The research plan should address activities to be conducted over the entire project period and must include the following:

Introduction/Background

- Describe the demographics (e.g., age, race/ethnicity, income, insurance status) of the pregnant clients served by the site(s) where the intervention will be implemented and evaluated. Include rates of smoking during pregnancy, and rates of fetal growth restriction and preterm birth.
- Describe the site(s) from which pregnant smokers will be recruited. Include prenatal health services provided to the target population at the proposed site(s), including (but not limited to) smoking cessation services offered during prenatal care either on-site, by referral, or available in the surrounding community. Include any clinic protocols specific to smoking assessment and cessation services.
- Describe the research team's experience developing and evaluating RCTs to evaluate smoking cessation interventions.
- Describe the research team's experience collecting medical cost reimbursement information and analyzing medical claims data.
- Describe the research team's experience working with the target population within the site(s) where the intervention will be implemented and evaluated, including experience of proposed staff.
- Demonstrate capacity to recruit the estimated number of prenatal smokers required for an adequately powered RCT.
- Describe experience retaining pregnant smokers, from the target population, in longitudinal studies. Include steps taken to locate participants that are lost to follow-up.
- Provide letter(s) of support from proposed site(s). In addition to a commitment to collaborate, the letter of support should identify proposed roles for site staff.

Specific Aims

- Specify overall aims or objectives for intervention development and evaluation.
- Specify primary and secondary outcomes, how they will be measured, and expected effect size.

Research Strategy

- Describe the RCT to increase smoking cessation among pregnant comparing CM and standard of care.
- Describe the inclusion criteria of study participants.
- Describe how the proposed intervention approaches or methodologies will be integrated into ongoing services at the proposed site(s).

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- Describe whether and how the proposed intervention will appeal to the target population, and how it will be culturally appropriate, including incentives that will be used.
 - Provide information on sample size calculations for the RCT. The RCT should be powered with respect to the primary outcomes (bio-chemically confirmed quit by end of pregnancy and cost-benefit) and must take into account the unit of randomization (e.g., individual, group).
 - Describe approach for recruitment and retention of the study participants.
 - Describe approach for randomization of study participants or sites, depending on the unit of analysis.
 - Describe method of data collection, management and quality assurance.
 - Describe how abstinence from smoking will be biochemically verified. It is required that abstinence from smoking be biochemically verified.
 - Provide a timeline for conducting follow-up assessments and collecting biological and behavioral data at baseline and subsequent time points during a minimum follow-up period of 6 months after delivery.
 - Describe how study data will be analyzed to compare abstinence at end of pregnancy and cost-benefit of the interventions using appropriate statistical methods.
 - Describe plans to share de-identified data with ISDH for secondary analyses.
 - Describe expected changes in biological and behavioral outcomes associated with the proposed intervention (e.g., specify baseline and post-intervention rates of smoking).
 - Describe expected contributions to the field (e.g., further understanding of CM interventions for pregnant smokers, potential for dissemination to and sustainability of the proposed intervention in the health care system).

Staffing and Milestones for Development and Implementation Phases

- Describe experience and expertise of key proposed staff, including ability to conduct a RCT using contingency management to increase smoking cessation among pregnant smokers and the ability to evaluate cost-benefit in a RCT.
- Identify tasks and a timeline for key intervention and protocol development activities to occur in the first 6 months of the project (i.e., development phase beginning of intervention implementation phase). Include milestones and/or measurable outputs that will be used to indicate progress toward having an Institutional Review Board (IRB)-approved protocol and all intervention materials pilot-tested, revised, and intervention staff trained within the first 6 months of the project.
- Identify key milestones and staffing needs for implementation of the RCT and cost-benefit evaluation (e.g., recruitment and enrollment, intervention delivery, data collection, data management, data analysis, report writing).
- Provide evidence of a clear management and staffing plan for all 3 phases: 1) Development; 2) Intervention implementation; and 3) Study findings, publications and dissemination.

Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available.

Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Applicants are **required** to submit applications electronically. For electronic submission:

Submit applications via email TO

Eden Bezy—MCH Substance Use Prevention Coordinator, at ebezy@isdh.in.gov

MAIL all supplemental materials that are unable to be sent via email to:

Indiana State Department of Health
Division of Maternal and Child Health
c/o Eden Bezy, MCH Substance Use Prevention Coordinator
2 N. Meridian St.
Indianapolis, IN 46204

*To ensure that your mailed supplemental materials are matched to your application, please write on the outside of the envelope your organization name, program name, and contact information.

Funding Restrictions

The following may not be claimed as project cost for MCH and CSHCN projects and may not be paid for with MCH/CSHCN or MCH/CSHCN Funds:

1. Construction of buildings, building renovations;
2. Depreciation of existing buildings or equipment;
3. Contributions, gifts, donations;
4. Entertainment, food;
5. Automobile purchase;
6. Interest and other financial costs;
7. Costs for in-hospital patient care;
8. Fines and penalties;
9. Fees for health services;
10. Accounting expenses for government agencies;
11. Bad debts;
12. Contingency funds;
13. Executive expenses (car rental, car phone, entertainment);
14. Client travel; and
15. Legislative lobbying.

The following may be claimed as project cost for MCH/CSHCN projects and may only be paid for with specific permission from the both the Director of MCH and the Director CSHC:

1. Equipment;
2. Out-of-state travel; and
3. Dues to societies, organizations, or federations.

All equipment costing \$1,000 or more that is purchased with MCH/CSHCN and/or MCH/CSHCN Matching Funds, shall remain the property of the State and shall not be sold or disposed of without written consent from the State.

For further clarification on allowable expenditures please contact: **Alisha Borcharding, MCH Grants Management**
aborcharding@isdh.in.gov

Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in section VII.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?

- Does the applicant address a scientific problem of great importance to public health research and/or practice?
- What is the potential or actual impact of the research on public health in Indiana?
- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Do the investigators provide evidence of successfully developing, implementing and evaluating RCTs for a contingency management intervention aimed at increasing smoking cessation among pregnant smokers?

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- Does the applicant demonstrate knowledge and experience of collecting medical cost reimbursement information and conducting a cost-benefit evaluation of intervention studies?
 - Do the investigators have adequate experience recruiting the targeted study population and retaining this population in an intervention study with follow up periods of at least **three** months after delivery?
 - Does the research team demonstrate experience working within the site(s) and collaborating on research studies with staff where the intervention will be implemented and evaluated?
 - Do the investigators have a successful track record in public health research?
 - Is there evidence of past collaborations with the proposed research team?
 - Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to ISDH?
- Does the application challenge and seek to shift current public health practice paradigms or approaches?
- Does the project have the potential to increase efficiency or lead to cost savings?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities justified in terms of the scientific goals and research strategy proposed?

- Does the application draw on the peer-reviewed literature and the applicant's own research to justify the proposed RCT and cost-benefit study design?
- Does the applicant describe their approach to finalizing intervention parameters, including definitions of primary and secondary intervention outcomes,

intervention approaches or methodologies for contingency management and cost-benefit and ensuring that the intervention is culturally appropriate and integrated into site services?

- Does the proposed RCT propose to use outcome measures that include bio-chemically verified cessation? Does the applicant describe training and quality assurance measures for conducting these bio-chemical tests?
- Are the participant recruitment strategy, study enrollment procedures, and retention strategies well described and adequate?
- Does the applicant provide power calculations demonstrating that the proposed sample size, taking into account anticipated attrition and the unit of randomization (e.g., individual, group), is sufficient to detect clinically meaningful differences between the RCT comparing CM and the standard of care?
- Does the evaluation design include collection of baseline data, end of pregnancy, and at least one follow-up data collection point during a minimum of *three* months of follow-up after delivery for individuals who have been randomly assigned to either the intervention or the standard of care?
- Does the applicant present an adequate plan for data management, including the linkage of questionnaire data with laboratory results?
- Does the applicant describe how study data will be analyzed to compare smoking abstinence at end of pregnancy and cost-benefit of the intervention using appropriate statistical methods?
- Is the proposed timeline sufficiently detailed, complete, and realistic for a 3-year project period (i.e., includes key tasks and staff responsible for intervention development, protocol development, and implementation of the RCT; and adequate milestones for measuring progress towards completion of these tasks)?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Does the applicant have access to qualified personnel with realistic and sufficient percentage-time commitments relative to each phase of the study timeline? Does the applicant describe clear lines of authority, responsibility and supervision for all aspects of the project?
- Does the applicant provide persuasive evidence that they can recruit and retain the estimated number of pregnant smokers needed for this project?
- Does the applicant describe the site(s) and staff, and explain how the physical infrastructure (e.g., lab, exam rooms, conference rooms), typical client flow, and

typical staff workload will contribute to and be affected by the implementation of the project, including the intervention itself and the data collection to evaluate the intervention?

- Does the letter of support from the study site(s) spell out the roles and responsibilities of the site(s) and their staff in the project (e.g., training and delivery of intervention, recruitment and follow-up of patients, data collection or access to data)?
- Does the applicant describe the information technology (equipment, software and expertise) available to the project (e.g., computers, software and programmer for assessments, computers and designer for web and other applications, software and expertise for analyses)?
- Does the application describe physical facilities and procedures for ensuring the confidentiality of the data? For securing the integrity and disposal of biological specimens (e.g., labeling, storage, transport)?
- Does the project support key stakeholder involvement throughout the research process?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans

Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review process, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.

Applications will compete for available funds with all applications submitted in response to this FOA. Following initial peer review, applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- The rate of smoking among pregnant women in the target population.
- The proportion of the study population that is disadvantaged economically.

Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be notified by May 15th 2013.

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk.

2. Cooperative Agreement Terms and Conditions of Award

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial ISDH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the ISDH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; ISDH Program Managers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and ISDH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Providing oversight of the management and administrative aspects of the project, including maintaining an adequate staffing plan to support project activities.
- Developing all materials required for IRB submission (e.g., protocol, consent forms, data collection materials, recruitment materials). The protocols must be designed to adequately describe implementation and evaluation of the proposed intervention and meet Office of Human Research Protections (OHRP) standards.
- Develop the research protocol and submit the protocol for human subjects review.
- Grantee will obtain local and site IRB approval for all collaborators.
- Developing recruitment strategies to enroll adequate numbers of the proposed study sample of pregnant smokers.
- Developing quantitative measures of outcome variables that include, but are not limited to, bio-chemically verified smoking cessation by end of pregnancy and cost-benefit ratios.
- Developing and implementing stringent safeguards for protecting the rights and confidentiality of participants.
- Obtaining all necessary permissions and/or clearances for the intervention materials.

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- Attending periodic meeting(s), as appropriate, at ISDH and elsewhere to develop and finalize the intervention and the research protocol, and provide progress updates.
 - Implementing the intervention, within the context of the evaluation/research study.
 - Identifying, recruiting, obtaining informed consent (or assent), and enrolling and retaining an adequate number of participants in the research, as determined by the study protocols.
 - Implement study.
 - Collecting all study data, including any laboratory tests that may be proposed.
 - Develop a process evaluation of key milestones of the project.
 - Ensuring data entry, security, and quality/accuracy.
 - Work collaboratively with ISDH staff on the design, analyses, and dissemination of study results, including sharing de-identified data with ISDH for secondary analyses.
 - Using appropriate statistical techniques to analyze data needed to evaluate the intervention.
 - Sending de-identified data to lead ISDH Investigator(s) over a secure data network.
 - Participate in monthly, or more frequently if deemed appropriate, conference calls with ISDH Investigator(s).

Awardees will retain custody of and have primary rights to the data and software developed under these awards..

ISDH staff will have programmatic involvement that is above and beyond the normal stewardship role in awards:

- An agency program official will be responsible for the normal stewardship of the award and will be named in the award notice.

3. Reporting

Awardees will be required to submit reports and financial statements annually.

Although the financial plans of the ISDH provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the State government.

A. Submission of Reports

The Recipient Organization must provide ISDH with an original, plus one hard copy of the following reports:

- 1. Yearly Non-Competing Grant Progress Report is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of ISDH provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented

in required reports) and the determination that continued funding is in the best interest of the State government.

2. **A final progress report**, invention statement, equipment/inventory report, and the expenditure data are required **within 90 days of the end of the project period**.

B. Content of Reports

1. **Yearly Non-Competing Grant Progress Report:** The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
 - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research to policy or practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*
 - How will the scientific findings be translated into public health policy or practice?
 - How will the project improve or effect the translation of research findings into policy or practice?
 - How will the research findings help promote or accelerate the dissemination,

implementation, or diffusion of improvements in public health programs or practices?

- How will the findings advance or guide future research efforts or related activities?
- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, policy, or use of technology in public health. *Questions to consider in preparing this section include:*
 - How will this project lead to improvements in public health?
 - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
 - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected
- New Budget Period Proposal:
 - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
 - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period.
- Publications/Presentations: Include publications/presentations resulting from this grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made.
- IRB Approval Certification: Include all current IRB approvals to avoid a funding

restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Final Reports: Final reports should provide sufficient detail for ISDH to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to promote, enhance or advance the research findings and the impact on public health policy and practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that influenced policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- **Public Health Relevance and Impact:** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, policy, technology, or systems improvement in public health.
- **Publications; Presentations; Media Coverage:** Include information regarding all publications, presentations or media coverage resulting from this ISDH funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

Maternal and Child Health

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