

Supporting Statement A

EMPLOYER PERSPECTIVES OF AN INSURER-SPONSORED WELLNESS GRANT

Request for Office of Management and Budget (OMB) Review and Approval
for a Federally Sponsored Data Collection

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June 14, 2016

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Attachment D: OHBWC - NIOSH Letter of Agreement.
Attachment E: Overall study description
Attachment F: OHBWC Workplace Wellness Grant Program Overview and Forms
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Attachment J2: Telephone script for Annual Case Study verification phone interviews
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Attachment L: Information Security Plan
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SECTION A. JUSTIFICATION

- Goal of the study: To determine the effectiveness and economic return of workplace wellness programs (that have been initiated via grant funding) on work-related injuries and illnesses, as measured by frequency of worker's compensation claims, and to understand the impact of integrating wellness with traditional occupational safety and health programs. The study will also gather information on how much employers are spending on their wellness programs in total (i.e., evaluate the fraction of overall wellness spending that the grant subsidizes per participating employee), and will evaluate how much paid employee time is being spent for wellness program management and participation.
- Intended use of the resulting data: Provide insurers and small employers with empirical data on the potential effectiveness of wellness programs initiated by insurer-sponsored grants in terms of total costs, savings and savings to cost ratios.
- Methods to be used to collect: This study is evaluating a natural experiment using 1) economic analyses to determine the total costs, savings, and savings (benefits) to cost ratios associated with wellness programs initiated with grant funding from the perspective of the grantor and the participating employers, and 2) quasi-experimental methods via a series of pre-post analyses.
- The subpopulation to be studied: Primarily small (<500 employees), private and public employers in the state of Ohio.
- How data will be analyzed: For the economic analyses the framework suggested by the CDC for developing a cost/benefit analysis. Other statistical analyses will be performed using multivariable Poisson regression.

A1. Circumstances Making the Collection of Information Necessary

Background

Work-related injuries and illnesses are common among US workers and result in pain, disability, and substantial cost to workers and employers. The latest available figures, published in 2011, placed the national economic burden of worker injuries and illnesses at \$263 billion based on a comprehensive analysis of the economic burden of medical and indirect costs for work-related injuries and illnesses. Workers' health is affected by

workplace safety and health hazards, employer practices, employer policies, and the work environment in addition to workers' own health behaviors.

This is a new information collection request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). This data collection is authorized by Section 20(a) (1) of the Occupational Safety and Health Act (29 U.S.C. 669) (Attachment A). NIOSH is requesting a one year approval to collect the information. This new ICR is one component of a larger project (Appendix E). The relationship between the goals of this ICR and the goals of the overall project are clarified in the next two paragraphs.

Furthermore, the full research project related to this ICR is one of many distinct, yet related projects dating back to 2010, when a formal partnership and collaborative research effort was renewed with the Ohio Bureau of Workers Compensation (OHBWC) began (Attachment D). To date, many projects being led by NIOSH project officers solely consist of subsequent analysis of data previously collected by the OHBWC. The data that OHBWC shares with NIOSH are data that they have collected in the course of conducted their business. The data are not required by NIOSH and are not considered federal collections. Several research studies have been completed and a number are ongoing with OHBWC, including a safety program assessment, material handling intervention effectiveness evaluation, safety services evaluation, and this project, an effectiveness evaluation of a Workplace Wellness Grant. Researchers across NIOSH are also conducting several claims-trending surveillance analyses focused on specific industries (temporary workers, mining industry, private industry ambulance services), causes (ergonomic-related, slip/trip/falls, machine-related injuries, nail gun injuries) and outcomes (traumatic brain injury). To date, five peer review publications have been completed, and over 30 other publications are planned with 20 different lead authors from both NIOSH and OHBWC.

To date, two other projects that are part of this overall partnership with OHBWC have required and received OMB approval. First, project 0920-0949, named, "Evaluating the Effectiveness of Occupational Safety and Health Program Elements in the Wholesale Retail Trade Sector," for which data collection has ended. Second, project 0920-0907, named "Musculoskeletal Disorder (MSD) Intervention Effectiveness in an Insurer-Supported Engineering Control Program," which expires on March 31, 2017. Each of these data collections are independent, however, there is some overlap between collaborators on each project and some workers' compensation data used for analyses that are being provided by OHBWC. This project has the benefit of using the lessons learned by our research team from working OHBWC data for over five years to when developing the project plan (e.g. study design, analysis plan) for the current project so some overlap exists in that respect even though the topic for this data collection is unique to this project to evaluate the effectiveness of the OHBWC Workplace Wellness Grant Program.

Historically, two different yet complementary approaches for protecting worker health and well-being exist in the workplace: Occupational Safety and Health (OSH) programs

and wellness programs. Both types of programs aim to improve worker health and may reduce costs to employers, workers' compensation (WC) insurers, and society. Since 2004 NIOSH has advocated integrated wellness programs and OSH programs as a holistic way to prevent work-related injuries and illnesses and improve worker's health. In today's evolving workplace employers cope with new types of work arrangements, an increasingly older workforce, and the narrowing line between work and home life that affect all workers' safety, health and well-being. The NIOSH Total Worker Health™ Office promotes research to advance the protection of worker safety and health, preservation of human resources, and promotion of worker well-being.

Limited evidence suggests that employers who integrate their wellness and OSH programs may have a greater impact on improving general health-related employee outcomes (e.g. tobacco use, blood pressure), absenteeism, and health care costs. However, few studies have evaluated the effect of integrated programs on work-related injury and illness incidence, severity and costs. There is a need for research to demonstrate a 'business case' for both wellness programs and integrated OSH-wellness programs and identify OSH organizational and management policies, programs and practices that effectively reduce work-related injuries, illnesses, disabilities and WC costs. To date small employers have been largely ignored in these areas and many studies have focused on the manufacturing industry. Real-world examples of effective interventions that apply to employers of all sizes and industries will ultimately improve workers' health and safety. This project addresses a priority goal of the NIOSH Total Worker Health™ Office — research comprehensive approaches that to preventing worker illness, injury and disease and to advance worker well-being.

Since 2010, NIOSH and the OHBWC have had a formal agreement (Attachment D) to collaborate on a number of common research goals, including descriptive WC data analyses, evaluation of prior OHBWC-sponsored programs, and prospective intervention research. As one of only four state-run WC insurance programs nationwide, OHBWC insures approximately two-thirds of Ohio workers. Larger employers (> 500 employees) are allowed to self-insure. OHBWC has many strengths as a potential research partner, including its size (approximately 250,000 insured establishments), diversity of industry that is largely representative of the larger US in both industry classification [based on general 2-digit North American Industry Classification System (NAICS)] and establishment size distribution, geographical proximity to the Cincinnati, OH and Morgantown, WV locations of NIOSH, and perhaps most importantly, their active engagement in intervention research. OHBWC represents an ideal translational research partner. OHBWC is an extremely pro-active WC insurance carrier; each year OHBWC spends millions of dollars supporting many programs to encourage insured companies to improve through tertiary OSH prevention programs. In summary, OHBWC has years of experience in developing, implementing, evaluating, and disseminating OSH programs with clients. Although OHBWC has actively engaged in prevention research, the organization is dedicated to demonstrating the effectiveness of their various programs using the most scientifically rigorous methods possible. For this reason, OHBWC has been eager to collaborate with NIOSH on a number of research projects including this

research study. In this way, evidence based practices can be shared with the greatest audience possible.

The proposed data collection is an important but relatively smaller effort nested within a larger study, Effect of Wellness Grant on Worker Health and Safety (Attachment E). For the current study, NIOSH and OHBWC are collaborating on a project to determine the effectiveness and economic return of OHBWC's Workplace Wellness Grant Program (WWGP) (Attachment F) and to understand the impact of integrating of wellness with traditional OSH programs. In early 2012 OHBWC took steps to integrate wellness and OSH programs by launching the WWGP, in which an estimated 400 (currently 321) small business employers (fewer than 500 employees) and 13,000 employees will be provided a total of up to \$4 million in funds over four years to implement new wellness programs (i.e., \$300 per participating employee over four years). This project provides a unique opportunity to leverage the OHBWC-NIOSH partnership to determine the effectiveness and economic return of the WWGP and to understand the impact of integrating of wellness with traditional OSH programs.

Overall, the study primarily consists of secondary analyses of data collected by our research partner, the OHBWC. The overall study will evaluate the 'business case' for both wellness programs and integrated OSH-wellness programs and identify OSH organizational and management policies, programs and practices that effectively reduce work-related injuries, illnesses, disabilities and WC costs.

This project is part of the mission of CDC-NIOSH to conduct rigorous scientific intervention effectiveness research to support the evidenced based prevention of occupational injuries and illnesses.

A2. Purpose and Use of Information Collection

The purpose of the data collection we are proposing is to provide important data to help address the need to 1) assess the effectiveness and cost-benefit of an intervention that funds workplace wellness programs among employers in Ohio insured by the OHBWC and 2) understand the impact of integrating of wellness with traditional occupational safety and health (OSH) programs. These needs are expressed in a number of NIOSH Strategic Goals (Federal Register Vol. 79, No. 184 (Tuesday, September 23, 2014; Attachments C1 & C2). Results of the study (in de-identified and aggregated form) will be disseminated in the scientific literature and in educational materials through NIOSH and OHBWC channels (website, publications).

The data collection for the WWGP evaluation study is part of a multi-year project between NIOSH and OHBWC that is fully funded from Fiscal Year 2014 through Fiscal Year 2017 (Attachment G). The project was awarded federal funds through the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research. If the WWGP is effective at improving worker health, reducing WC claims and demonstrating a positive economic return, then other employers and insurance carriers

may develop similar programs and drive the optimization of integrated OSH-wellness approaches.

The overall study has three, multi-part, specific aims:

1. Measure effectiveness of the WWGP implementation by comparing data from pre-post-implementation of a wellness program on the following outcomes: **a)** WC claim, severity (days lost per claim), and cost rates, **b)** aggregate health metrics for participant employees by employer [health risk assessment data (e.g. percentage of smokers, percentage of participants with > 4 specific health risk factors) and biometric data (e.g. percentage of participants with high blood pressure)], **c)** absenteeism rates, **d)** turnover rates, and **e)** health care cost per employee
2. Determine the relationship between WC claim rates and changes in yearly pre- and post-intervention measures for **a)** OSH program elements, **b)** wellness program elements, and **c)** OSH-wellness program integration measures
3. Determine the total costs, savings, and savings (benefits) to cost ratios associated with grant-supported wellness programs from the perspective of OHBWC and the participating employers.

From the overall study specific aims listed above, the proposed data collection will be used to address Aim 2c and for Aim 3. In particular, this ICR is key to Aim 3 because the information gathered will be the only data that can be used to quantify the investment being made by the participating employers that is not being paid for by the WWGP. To maintain continuity with the numbering used in Appendix E, the same aim numbers have been retained in this document. It follows that the two specific aims for this ICR are:

- Aim 2.c) Determine the relationship between WC claim rates and changes in yearly pre- and post-intervention measures for OSH-wellness program integration measures.
- Aim 3. Determine the total costs, savings, and savings (benefits) to cost ratios associated with grant-supported wellness programs from the perspective of OHBWC and the participating employers.

This data collection is justified because although there is an increasing evidence base for the effectiveness of wellness programs and the integration of wellness programs with traditional OSH programs in improving employee health[1, 2] and reducing health care costs and absenteeism[3, 4], few studies have investigated the impact of such programs on work-related injuries and illnesses[5], especially by quantifying reductions in WC claim frequency and costs[6-12] and conducting rigorous evaluations of economic return from the perspective of the insurer and the employer.

Cost information collected during the semi-structured economic interviews is required for estimating economic return from both the insurer's perspective and the participating employer's perspective. Because there are only minimum criteria set by OHBWC for each grantee's wellness program, there have been a broad range of programs implemented at the employer level. The OHBWC grant is for a relatively small amount of funds (\$300/employee over four years), because OHBWC expects employers to use

the funds as seed money to start their wellness program. The amount of funds provided per employee decreases across each year because OHBWC expects the employer to provide a greater majority of wellness spending for their employees during the grant period. Total wellness program costs are expected to exceed the amount that employers receive in grants from OHBWC. For this reason, we need to conduct these in-depth interviews to gather information on how much employers are spending on their wellness programs in addition to the grants, and how much paid employee time is being spent for wellness program management and participation.

After each funding year OHBWC measures the degree and level of naturally occurring integration between an employers' OSH and wellness programs via a self-administered annual survey that a key informant submits to OHBWC. The survey is a required element of participating in the grant program and is not part of any federal data collection. The data from Section II, the *OSH-Wellness Integration Module*, of the survey are used to measure the level of integration between OSH-wellness in the workplace across eleven dimensions: 1) wellness program activities funded by the grant; 2) other wellness or OSH program activities offered by the employer to support their wellness program; OSH-wellness integration of 3) program planning, 4) evaluation, 5) data used to monitor programs, 6) communication materials, 7) training sessions, 8) program implementation decisions, 9) personnel who are responsible for implementing wellness or OSH programs, 10) decision makers who influence program design or implementation; and 11) perceived work factors that could be barriers that make it more difficult for employees to exercise or eat healthy food. Although OHBWC implemented the *OSH-Wellness Integration Module* in 2012, there is substantial overlap between the eleven dimensions and recent recommendations in the literature for measuring integration{Williams, 2015 #2725}. More detailed information about how the data from these survey questions are used to measure integration is described in section A16.A.

The questions in Section II on OSH-wellness integration were adapted where possible from existing sources (e.g., Safewell, SIMS checklist) and the length of the survey was designed to minimize employer burden. The survey/annual case study that OHBWC is using to measure integration as part of their WWGP program is one of the first of its kind. It was developed quickly to meet the demands of the grant program rollout schedule, and launched without evaluation of the survey questions with potential respondents. The questions were specifically designed for this population of respondents, as no publicly available OSH-Wellness Integration surveys are available that would work for evaluation of WWGP participating employers. In 2014, NIOSH investigators reviewed preliminary data from the first year annual employer survey and the first six economic interviews, and concluded that it would be ideal to contact a sample of employers and confirm that the survey questions were understood correctly and responded to appropriately. We also concluded that a question about why the employer decided to establish a wellness program could help provide insight into how the overall costs and benefits of establishing a wellness program were perceived by employers at the outset, and the extent to which a cost and benefit perspective was important in decision making.

The results of these interview-supplemented case studies will be used to estimate the average proportion by which total employer costs exceed the cost of the primary wellness program vendor, as well the proportion of these costs attributable to establishing the program in the first year versus operating the program in subsequent years. These estimates will be applied to generate total employer costs for all of the WWGP recipients, with sensitivity analyses based on the observed variability of employer costs in the case studies.

Work is needed to better understand and validate responses to the annual survey each grantee submits after each funding year to OHBWC. Information collected from the annual case study verification telephone interviews will be an additional element in this study used to examine the validity of the survey questions, especially the questions about integration. If we find that some questions were frequently misunderstood, then those questions may be dropped from any statistical analyses, or results will be interpreted accordingly. For example, based on preliminary analyses, it seems possible that employers are more likely to skip some of the questions about perceived work factors that make it difficult for employees to exercise or eat healthy. It is possible that most employers are not comfortable answering that type of question because they don't know what most employees think.

Analysis of the annual case study data is vital to conducting a rigorous evaluation of how effective OSH-wellness integration can be for improving worker health and reducing WC claims. With the results from this study, we will be able to identify best practices and economic returns for the most effective wellness and OSH-wellness integrated programs. Real-world examples of effective interventions that apply to employers of all sizes and industries will ultimately improve workers' health and safety.

Very few wellness grant programs sponsored by insurers exist. Clearly there is a need to conduct rigorous research to define further the effectiveness of this insurer sponsored WWGP. The goal is to identify evidence based practices and programs that can be shared with the greatest audience possible. In this way, OHBWC can efficiently allocate their resources. For this reason, OHBWC has been eager to collaborate with NIOSH on this project. OHBWC and NIOSH have also formalized an agreement (Attachment D) to outline a collaborative research partnership and specify a data sharing agreement to ensure data security. This WWGP effectiveness study represents one of the key steps towards addressing many of the partnership goals and OHBWC is committed to supporting this project (letter of support from OHBWC in Attachment H).

Such data has practical utility to the federal government, state government, and private stakeholders. At the conclusion of the project, NIOSH will communicate our findings with employers across all sectors (including the Federal sector) to ensure that workplace health protection and health promotion programs incorporate empirical evidence to adopt, incorporate and advance effective Total Worker Health™ policies, programs and practices.

Outputs related to this data collection include, but are not limited to, the following:

- 1) a report to OHBWC summarizing lessons learned from the semi-structured economic interviews;
- 2) an article presenting results of the annual case study data analysis;
- 3) an article presenting the business case for the WWGP in terms of total costs, savings and savings to cost ratios;
- 4) conference presentations (Ohio Safety Congress/ national);
- 5) NIOSH will work with OHBWC to summarize the lessons learned about the WWGP and develop best practices for the implementation of workplace wellness programs, especially among small employers;
- 6) OHBWC will also use this research to develop and disseminate prevention materials and provide targeted assistance (safety/ ergonomics / wellness consultation and training) in their ongoing OSH outreach to small and large businesses.

Target audiences for outputs will include employers, professionals (professional organizations for safety and health, risk management, health benefits, human resources and health promotion), and industry leaders.

There may be an increase in OHBWC activities to promote workplace wellness or the integration of wellness with occupational and safety programs based in part on the findings of this project and the continued collaboration with NIOSH on Total Worker Health™ initiatives.

The results of the current study are also relevant for private employers, WC carriers, or health insurance carriers that may sponsor prevention programs. Premium discount programs for developing OSH programs are currently rare among private insurance companies. If a rigorous study can determine the level of effectiveness of such a program, other insurance companies may utilize this data to determine whether such a program should be implemented or expanded.

A3. Use of Improved Information Technology and Burden Reduction

Semi-structured economic interviews are being used to assess employers' total cost for their wellness programs relative to the wellness grant money received from OHBWC as an important component of estimating economic return from both the insurer's perspective and the participating employer's perspective. The assessment requires accurate estimates of total program costs which are expected to exceed the amount that employers receive in grants from OHBWC. NIOSH and OHBWC are conducting these in-depth, economic, semi-structured interviews with no more than 25 randomly selected participating employers. These are questions that can only be captured by conducting interviews like this to employers about time, effort and other expenses beyond what was funded by the WWGP.

There are several reasons why our research team believes that taking the time to conduct in-person interviews is the best way to collect the information we need. First, different

employers may have information in different forms, so that one standard survey question may not be sufficient to capture the relevant information. For example, employers might have information about budgets by individual program element or for the program as a whole; or employers might be better able to estimate time spent on their program by activity or for the program as a whole and for shorter or longer time frames. Second, we expected that, in many instances, employers may not have all the information we wish to collect. In that case, an interview setting offers the opportunity to probe for the employer's best judgment or for information at a less detailed level that could be more useful than a non-response. Third, the degree of precision and uncertainty of estimates might be better ascertained in person. Responses that are not clear, or that indicate uncertainty can be clarified with follow-up questions. Fourth, the conversational format also elicits unanticipated, important information and perspectives and allows interviewers to explore responses in more detail. We have already seen this in our first 6 pilot interviews.

A4. Efforts to Identify Duplication and Use of Similar Information

To date, NIOSH is aware of only one other wellness program sponsored by a WC carrier to their clients. That program, offered by Pinnacol Assurance to employers in Colorado is fundamentally different from the Ohio program because the insurer controls the intervention and all employers received the same somewhat limited intervention. Pinnacol Assurance is working with a research team at the University of Colorado to evaluate the effectiveness of their program, but the researchers are not allowed to have direct contact with employers, so economic return analyses would not be as comprehensive as the ones planned for this study. Also, that evaluation does not include a measure of integration between an employer's wellness program and their OSH program. Most other wellness intervention studies have been evaluated at the participant level for one large employer and may not represent the experience of small employers. This OHBWC WWGP study population is unique in that participants are mainly smaller employers (most are < 100 employees) and because there are so many (>250) employers.

As stated in Section A2, similar information about OHBWC policies and claims is being used by other projects as part of an ongoing collaborative research partnership. Some claims and policy-level data collected by OHBWC are being used for analyses being conducted for the overall WWGP evaluation project as well as two other Federal studies approved by OMB (OMB control numbers 0920-0949 and 0920-0907. These data are part of an OHBWC-NIOSH data warehouse databases being maintained by NIOSH for use on multiple projects across NIOSH.

A5. Impact on Small Businesses or Other Small Entities

Only small, OHBWC-insured businesses with fewer than 500 employees will be included in this study. We are limiting the interviews to a pool of 25 employers for the semi-structured economic interviews, which will last an average of two hours, including

preparation. Typically only one key informant will be participating per employer but we estimated two per employer for a more conservative burden estimate. In the first six interviews there has only been one situation where more than one key informant participated in the interview, although we expect that when a separate person is in charge of occupational safety then that person may have been consulted prior to the interview or briefly during the interview. For the annual case study verification telephone interviews we are limiting the interviews to a pool of 50 employers, for 1-2 interviews that may last up to 30 minutes, therefore up to 100 key informants may be contacted. Participation in either interview is voluntary and we expect that key informants at small employers who think this time commitment will be a burden for them or their employer will choose not to participate in the interviews.

A6. Consequences of Information Collected Less Frequently

The planned frequency of a single data collection per employer is already at a minimum level to reduce burden on respondents for the semi-structured interview. For the annual case study verification interviews we may talk to the same employer up to two times but even then the total burden for that employer is an hour rather than 30 minutes.

There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection activity. This request fully complies with regulation 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8.A: 60-day Notice

In accordance with 5 CFR 1320.8(d), a review of the proposed study was sought through a 60-day publication period in the Federal Register/Vol. 80, No. 85, pages 25296-25298 (Monday, May 4, 2015) (Attachment B). CDC did not receive public comments related to this notice.

A8.B: Consultations outside the agency

NIOSH has consulted with external stakeholders outside the agency regarding the availability and usefulness of the proposed data collection. Stakeholders included representatives from OHBWC (2009-2010, 2014-2015) and peer reviews in March 2012 by the NIOSH Safety and Occupational Health Study Section as part of the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research, and informal feedback after presentations at three scientific conferences ((the 1st International Symposium on Total Worker Health™ in Bethesda, Maryland in October, 2014; Work, Stress and Health 2015). In addition, prior to launching the WWGP,

OHBWC spent months meeting with various stakeholders in the state to get input on how the program would work.

One criticism of the proposal was that nine semi-structured economic interviews was not an adequate sample to estimate what employers were spending on their wellness programs and it was strongly recommended that we conduct more interviews so that the sample can be more representative of the entire population of grant recipients included in the study. We agreed with the review and decided that a minimum of 25 interviews would be an adequate and feasible goal for our research team if we obtain OMB approval.

The following staff at the OHBWC were consulted:

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The review panel for the NORA Fiscal Year 2014 process is listed below.

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There were no major unresolved problems identified during any consultation with anyone outside of CDC.

A9. Explanation of Any Payment or Gift to Respondents

Participants will not be given gifts or payments to complete the interviews.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC's Information Collection Review Office has reviewed this application and has determined that the Privacy Act is applicable. Information in Identifiable Form (IIF) will be collected by OHBWC and maintained and secured by NIOSH. The relevant Privacy Act System of Records Notice (SORN) is System name: Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH (<http://www.cdc.gov/SORNnotice/09-20-0147.htm>).

An overview of the data collection system

Semi-structured in person (economic) or unstructured telephone (annual case study verifications) interviews will be used to collect data for this study. NIOSH employees or contractors will primarily conduct the data collection and data management. Information will be maintained until two years after the conclusion of the overall study.

NIOSH and OHBWC are conducting these in-depth, economic, structured interviews with 1-2 key informants from no more than 25 randomly selected participating employers.

These semi-structured interviews (Attachment J1) will be administered once to up to 50 key informants from 25 randomly selected employers that received grant funding from the WWGP. Based on pilot-testing, it is estimated it will require the key informant an average of 30 minutes to prepare for the interview and an average 90 minutes (up to a maximum of 120 minutes) per interview. With consent from the interviewee(s), a digital recording of the interview will be made using a portable digital voice recorder. Digital recordings of interviews will be transferred to a secure network drive after the interview, then used to supplement and check notes taken during the interview. After NIOSH is done taking and checking notes the electronic files will be deleted from the digital voice recorder and eventually deleted permanently.

These telephone interviews (Attachment J2) will be administered 1-2 times per employer, so up to 100 key informants may participate from randomly selected employers that have received grant funding from the WWGP and are not participating in the semi-structured economic interviews.

Information in identifiable form (IIF): Documentation from the interview does not contain individual names. No IIF will be collected as part of the actual interviews. However, for recruiting and scheduling purposes, the following IIF will be collected from OHBWC separately from the interview: 1) interviewee's first and last names, 2) employer addresses for the interview location, 3) interviewee phone numbers at the employer, and 4) interviewee email addresses at the employer. The IIF will be maintained by NIOSH in a separate, secure database to coordinate contacts at each employer. Finally, the first and last name of the interviewee will be used to send a hard copy of aggregated study results if requested by the individual.

The attached interview guides provide detailed information on the topics included in both the semi-structured economic interviews (Attachment J1) and the annual case study verification interviews (Attachment J2)

As described, the proposed research will involve the collection of information through in person or telephone interviews. The research will not direct any website content at children under 13 years of age. All data collection and records management practices and systems (including the online survey system) will adhere to all applicable federal, Health and Human Services (HHS), Centers for Disease Control (CDC), and NIOSH IT security policies and procedures [Security Requirements for Federal Information Technology Resources, January 2010; Health and Human Services Acquisition Regulation (HHSAR), Clause 352.239-72]. See the Information Security Plan in Attachment L for more information.

Individual interviewee or employer specific information will not be published in any identifiable form and will be protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). Disclosure under the Privacy Act System is permitted: to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct further investigations; to the Department of Justice in the event of litigation; and to a congressional office assisting individuals in obtaining their records.

The interview will collect information about wellness program costs and occupational health program costs. Risks to interviewees are low since no IIF is being collected as part of the actual interview, but rather the information collected by OHBWC will be maintained by NIOSH in a separate secure database to coordinate contacts at each employer. Each employer that enrolls in the study will be subsequently identified only with a code on all other information collection forms. Several controls (safeguards) will be put into place to minimize the possibility of unauthorized access, use, or dissemination of the information being collected.

Key informants will be informed that their participation is voluntary, and that they may discontinue the interview at any time. They will also be advised that they will not lose any benefits to which they are otherwise entitled if they chose not to participate.

The Employer Participation Information sheet (Attachment M) includes an explanation that participation in this study is voluntary: “The interview is voluntary. You may choose to be interviewed or not. You may choose to answer any or all questions. You may choose not to have the interview recorded. You may stop the interview at any time for any reason without consequences to you or your organization.” All key informants for the semi-structured interviews receive this document well in advance of the scheduled interview. Key informants responding to the annual case study verification phone call will be given the same information verbally.

Individual interviewee personal or employer-specific information will not be published in any identifiable form and will be protected to the extent allowed by law (Freedom of Information Act and the Privacy Act).

To conduct the semi-structured economic interviews (Attachment J1) and the annual case study verification interviews (Attachment J2) NIOSH will maintain personal identifiers (respondent name, employer address, respondent phone number at the employer, and respondent email address at the employer) in a separate secure database to recruit and schedule interviews for each employer.

Planned controls are summarized in the table below.

Control Descriptions	Control Type
<ul style="list-style-type: none"> • User Identification • Passwords • Firewall • Virtual Private Network (VPN) • Encryption • Intrusion Detection System (IDS) • Common Access Cards (CAC) • Smart Cards 	Technical
<ul style="list-style-type: none"> • Guards • Identification Badges • Key Cards • Closed Circuit TV (CCTV) 	Physical

<ol style="list-style-type: none"> 1. Security Plan: The system security plan for this information collection is detailed in Attachment L. 2. Contingency Plan: Files be backed up will be backed-up weekly using an offsite Microsoft SQL server based in Atlanta, GA CDC offices. 3. Personnel Training: All CDC and contract personnel (principal investigator, managers, operators, contractors and/or program staff) will receive yearly training using the system and made aware of their responsibilities for protecting the information being collected and maintained. 4. Contractor Adherence: Contracts for staff that operate or use the system will include clauses ensuring adherence to privacy provisions and practices. 5. Access Levels: Methods will be put into place to ensure the least privilege possible (e.g., access is “role based” on a “need to know” basis). Accountability will be ensured through yearly security reviews. 6. IIF Policy: There are CDC policies or guidelines in place with regard to the retention and destruction of IIF. 	Administrative
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Access to individual data used for contacting participating employers will be limited to authorized NIOSH researchers and contractors. Physical controls: NIOSH facilities have 24-hour security guards, and key card ID badges must be used to enter the buildings. Data in hardcopy form will be stored in locked rooms or cabinets. Technical controls: all electronic data will be stored on secure servers that are protected with firewalls and passwords. Any contractor charged with data collection, preparation, or management tasks to be performed away from a NIOSH facility will be required to follow equivalent procedures.

The process for handling security incidents is defined in the system's Information Security Plan (Attachment L). Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate

The only data being collected for this study are employer level economic data collected from no more than 25 structured interviews with participating employers and the information collected by telephone to verify previously submitted annual case study data.

The IIF used for recruiting and scheduling purpose are kept in a separate secure database to recruit and schedule interviews for each employer.

Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule (see <http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy449.htm>).

A11. Institutional Review Board (IRB) and Justification for Sensitive Question

We have received IRB approval for the overall study (Attachment I), however this study involves the analysis of previously collected, coded workers compensation data, aggregate health risk appraisal data, aggregate biometric data, and employer level economic data. The interviews will not involve any contact of individual participants for individual data. Therefore, no human subject's data will be collected during either interview. The Employer Information sheet that all semi-structured interview participants are given explains who is conducting the study, the purpose of the study, what will happen during the interview, how to prepare for the interview, the duration of the interview, risks to participation, the voluntary nature of the interview and any potential benefits, how the (de-identified and aggregated) results will be used, and who to contact with questions (Attachment M). Waiver of informed consent (for adults, assent for children capable of providing assent, and parental permission) was approved by the NIOSH IRB. The study involves minimal, if any, risk to the participants. The only potential risks pertain to release of individually identified information and appropriate safeguards are in place to protect against such release, as indicated in the records management section below. The study protocol (Attachment E) meets the elements of the criteria stated in 45CFR46 116 (d) (1) (2) (3) and (4) for waiving the requirement to obtain written informed consent.

The proposed interview questions contain no questions that may be considered personally sensitive. Answering any questions poses little risk to the individual respondent since no data in individually identifiable form (IIF) is being collected during the interview.

A12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

No direct costs will accrue to respondents other than their time to prepare for and participate in the interviews. It is estimated that a maximum of 150 individuals will be interviewed (up to 50 for the semi-structured economic interviews and up to 100 for the annual case study verification interviews). The economic interviews include the wellness program coordinators and the Occupational Health and Safety Specialist. The hour-burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and participating in the interview. Hour-burden estimates for the economic interviews were derived from six pilot interviews.

Table A.12-1. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
Wellness Program Coordinators	Employer interviews on cost of wellness and occupational safety and health program	25	1	2	50
Occupational Health and Safety Specialists	Employer interviews on cost of wellness and occupational safety and health program	25	1	2	50
The person in charge of the employer's wellness program	Annual case study verification interview	100	1	.5	50
Total Hours					150

B. Annualized Cost to Respondents

The total estimated annualized cost to respondents is \$7,005, as summarized in Table A.12-2. We used mean hourly wage data from the Bureau of Labor Statistics, May 2013 National Occupational Employment and Wage Estimates for the estimated annualized costs. The mean hourly wage rate for Human Resources Manager of \$53.45 was used for the Wellness Program Coordinators and the person in charge of the employer's wellness program because we have found that often the key informant is the Human Resources Manager so this would give us a conservative burden estimate. Sometimes the person in charge of the wellness program asks for help from an occupational health and safety staff to prepare for or answer some of our questions so the mean hourly wage for Occupational Health and Safety Specialists of \$33.20 was used for this estimate as well. Most of the time we do not anticipate that more than one person will participate in preparing for and participating in the economic interviews.

United States- Table 3. Hourly mean wage rates by industry and occupational group, May 2009).

Table A.12-2. Estimated Annualized Cost to Respondents

Wellness Program Coordinators	Employer interviews on cost of wellness and occupational safety and health program	50	\$53.45	\$2,672.50
Occupational Health and Safety Specialists	Employer interviews on cost of wellness and occupational safety and health program	50	\$33.20	\$1,660.00
The person in charge of the employer's wellness program	Annual case study verification interview	50	\$53.45	\$2,672.50
Total				\$7,005.00

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs to respondents.

A14. Annualized Cost to the Government

Total costs to be incurred to conduct the interviews includes work performed over the course of four years by CDC research personnel (1 industrial hygienist, 2 epidemiologists, 1 economist) and contracted personnel, including tasks such as: (1) development of interview materials; (2) development of sample selection; (3) interview recruitment and scheduling; (4) conducting interviews; (5) data entry; (6) data processing and management; and (7) data analysis. Estimated annualized costs to the Federal Government for the survey period are presented in Table A.14-1 below.

Table A.14-1. Estimated Annualized Cost to the Federal Government

	FY2014	FY2015	FY2016	FY2017	PROJECT	Annualized Cost
Personnel Salaries and Benefits	\$10,878	\$10,766	\$26,414	\$25,652	\$73,711	\$18,428
Intramural Contractual	\$0	\$1,288	\$955	\$765	\$3,007	\$752
Travel	\$900	\$450	\$1,500	\$900	\$3,750	\$938
				TOTAL	\$80,468	\$20,117

^a Includes a 3% personnel cost of living salary increase per year

The annualized cost to the Federal Government is \$20,117

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

A16.A. Analysis Plan

Data collection will be completed over one year, followed by statistical analysis and dissemination of data. A full description of the statistical protocol is provided in Part B1

and B2 of this ICR. Refer to Attachment E for a description of the overall project, including a description of all the data that we will be receiving from OHBWC and statistical methods for the overall project.

Results from each specific aim of this project will be disseminated throughout Ohio and nationally through four main channels:

- OHBWC (website, publications, annual safety congress, Safety Council meetings and personnel):
 - The OHBWC has a developed infrastructure to reach employers within the state of Ohio.
 - NIOSH and OHBWC have a formal agreement in place and this project will leverage this collaboration to solicit input from employers and provide results as they become available.
 - OHBWC and NIOSH will cross promote each other's resources as much as possible. A main method for this dissemination will be the OHBWC website (<http://www.ohiobwc.com>) and several joint OHBWC-NIOSH publications (such as wellness program effectiveness for small business) are planned.
 - OHBWC offers monthly Safety Council meetings in most counties throughout Ohio and a free yearly safety congress where presentations and workshops about the studies will be conducted.
- NIOSH (website, publications, and personnel): links to the same dissemination products outlined in the OHBWC section above will be cross promoted on the NIOSH website.
- Trade Organizations (website, publications, and personnel): links to the same dissemination products will also be provided directly to several trade organizations. Aspects of the studies will also be submitted for publication in trade journals.
- Peer reviewed journals: there will be at least three manuscripts submitted to peer reviewed journals. The main audiences for these types of journals are fellow researchers, but also OSH practitioners.

Data Available

As requirements for the WWGP, employers must submit at baseline and annually: non-WC related aggregated employee health care cost data, aggregated participant employee absenteeism and participant employer turnover data. Employers must submit an annual narrative case study to assess safety, wellness, and claims management activities and to assist with establishing best practices for the implementation of workplace wellness programs. OHBWC will provide NIOSH with grant program records, including the employer's wellness program vendor invoices and any other expenses supported by the grant funding. Employers must allow the OHBWC to inspect original employer WWGP records upon demand and on site in the event that questions arise regarding the participation in the WWGP. In addition to the employer-provided data, NIOSH will obtain other OHBWC data for all employers: WC claims, claim severity, and cost data for all OHBWC-insured employers, data that details employer participation in other OHBWC programs (safety grants, safety council memberships, drug-free safety programs etc.), North American Industry Classification System (NAICS) codes, and employer size category (1-10, 11-49, 50-250, 250-500, 501+ employees), and the number and hours of OHBWC onsite consultations. Annual OSH and wellness program self-assessment data are available for approximately 9,000 employers who fill out the OHBWC safety

management self-assessment survey (SH-26) as part of their participation in other OHBWC programs (e.g. Industry Specific Safety Program, Drug-Free Safety Program). Data from Non-WWGP Employers who have submitted SH-26 data to OHBWC and self-rated themselves as 'low' on the quality of their wellness program will be used to randomly select matched controls for WWGP Employers, for Aim 1.

Specific Aim 3 Analysis

Aim 3: Determine the total costs, savings, and savings (benefits) to cost ratios associated with grant-supported wellness programs from the perspective of OHBWC and the participating employers.

Costs: Grant program records and reports from employers will provide information in each of the four years on the cost of each employer's wellness program vendor and the shares of this cost paid by the employer and by the grant from OHBWC. OHBWC will also be able to provide estimates of its own cost of planning and administering the program. However, there are additional costs to the employers that will have to be gathered by other means.

NIOSH is conducting in-depth, structured interviews with at least nine and up to 25 participating employers, pending OMB approval. The focus of the interviews is described in detail elsewhere in this document. The results of these interview-supplemented case studies will be used to estimate the proportion by which total employer costs exceed the cost of the primary wellness program vendor, as well the proportion of these costs attributable to establishing the program in the first year versus operating the program in subsequent years. These estimates will be applied to generate total employer costs for all of the WWGP recipients, with sensitivity analysis based on the observed variability of employer costs in the case studies.

Savings: Savings will be calculated in the categories of WC costs, health care costs, and absenteeism costs. Reductions in turnover will also be calculated, but will not be converted to dollars, because the cost of turnover depends upon a variety of employer and job-specific factors, and the detailed information needed is impractical for employers to provide. The savings in WC costs as viewed by OHBWC are the total cost of claims averted, including administration costs. Reductions in total claim costs will be estimated as described for Specific Aim #1 of the overall study (Attachment E). The cost of claims that occur during the 4-year study period will be measured at least 30 months post injury, as is standard practice for analysis of claims costs. This means that the full WC claim cost saving analysis will occur in approximately FY18.

The savings in WC costs as viewed by non-self-insured employers is the reduction in WC insurance premiums. Estimates of reductions in claims per 100 employees and claim costs per 100 employees associated with wellness programs, as described above, will be used to estimate reductions in premiums as given by the standard experience rating formula. Because this formula is based on claims experience over several years, the

premium savings will also be realized over a period of several years following the averted injuries and so will also be discounted at appropriate discount rates. Depending upon the claims record, industry, size, and other factors, employers may also experience premium reductions due to qualifying for group discounts, and the potential for these savings will also be characterized.

Employers will provide four years of past health care costs data and health care costs in each of the four years of the study period (subject to availability). Declines (or increases) in these costs attributable to the wellness program will be estimated, following the methods described for Specific Aim #1 of the overall study (Attachment E). For non-self-insured employers who provide or contribute to health insurance policy for their employees, their share of health care costs is borne indirectly through payment of insurance premiums and with a time lag. It is beyond the scope of this project to collect specific information from employers to determine the impact of health care costs on insurance premiums. However, illustrative calculations can be done based on inquiries with insurance carriers about their rating practices, and taking cognizance of Ohio rating restrictions that apply to employers with 50 or fewer employees. The cost of insurance as a ratio to the cost of claims, as well as the average share of premiums paid by employers can be ascertained for employers nationally from published research based on the Medical Expenditure Panel Survey, the annual employer survey of the Health Insurance Association of American (HIAA), the National Compensation Survey, and other sources.

Absenteeism savings calculations will be based on the estimated change in days of absence per employee per year as estimated by methods described under Specific Aim #1 of the overall study (Attachment E). Days of absence can be converted to dollar values, by valuing lost time with the daily cost of employee compensation. Compensation per day is available from OHBWC which uses this information on WC claimants in order to calculate their indemnity benefits. Research has found that the cost of absence is somewhat greater, on average, than the cost of compensation, because unplanned absence can be disruptive of work teams under pressure to meet delivery schedules, so findings from this research will be used to estimate this additional component of cost as a proportion of compensation.

Discounting

Calculation of Present Values of Costs and Savings: Wellness program expenditures do not generally create tangible assets, but they do, in part, represent an investment in at least two senses. First, the effort of planning and initiating a program is expected to bear fruit not just in the first year, but in subsequent years as well, as the workplace health culture and the routines of health program activities are institutionalized. Second, the health behavior improvements of each year cumulate to create future health benefits. Thus, total costs and total savings need to be viewed not just year-by-year, but over the entire four years encompassed by this project. Because costs and savings of future years are not valued as highly as those of the present year, discounting future costs and savings is necessary for a proper valuation. This is especially important, since costs may be higher in the first year, but savings may be higher in later years, as impacts on health and injury rates build on gains in previous years.

This study will follow the framework suggested by the CDC for developing a cost/benefit analysis. Both costs and benefits (savings) will be discounted to yield the present values of each. The relationship between savings and costs can then be expressed as a ratio that is useful for comparing results across employers and wellness programs of different sizes. Ratios will be computed separately for each component of savings, and for aggregate savings. The difference between discounted costs and savings, or net present value (NPV) can also be computed. This will be a partial cost/benefit analysis, since not all savings will be estimated. For this study, a discount rate of 7% will be used, since that is the standard discount rate recommended by the Office of Management and Budget for evaluating government investments (OMB). However, because investments in public health are often discounted at 3% and private employer investments are often discounted at rates higher than 7%, calculations with alternative discount rates will be performed. Separate analyses of costs, savings, and benefit/cost ratios for wellness programs will be performed from the perspective of employers and OHBWC. The data collected during the in-depth, semi-structured economic interviews is vital to conducting the cost-benefit analyses from the perspective of the insured employers. Information gathered from key informants about program costs and time spent running the program can be combined with other information that we know about other employers to help estimate employer costs not covered by the WWGP. Analyses will be done based on actual share of program costs, but can also illustrate how costs and their relationship with savings could change with different formulas for cost sharing between OHBWC and employers.

Specific Aim 2.c) Analysis Plan

Aim 2.c): Determine the relationship between WC claim rates and changes in yearly pre- and post-intervention measures for OSH-wellness program integration measures.

This aim of the research involves an employer-level survey of a series of organizational safety, health, wellness, and OSH-wellness program integration metrics. A key informant at each employer will complete surveys for OHBWC to evaluate organizational metrics related to their employer's wellness program, OSH program, and OSH-wellness program integration after each year of program participation. The contents of the OSH-wellness integration survey are summarized below.

Data description

This aim uses data collected by OBWC from an employer-level survey/annual case study (Attachment K) of organizational wellness and OSH-wellness program integration metrics. After the employer has been in the study one year, an individual at each employer will complete a survey/annual case study to evaluate organizational metrics related to their employer's wellness program and level of OSH-wellness integration. The survey includes two sections, Section I contains 19 descriptive questions about the organization as a whole and a variety of questions about their wellness program: aggregate data about employees who participated in the wellness program, descriptive information about program elements and evaluation methods, challenges in the past year, goals for the next year, information about their vendor. Section II is the eleven question *OSH-Wellness Integration Module* that asks questions about wellness program activities

funded by the grant; other wellness or OSH program activities offered by the employer to support their wellness program; OSH-wellness integration of program planning, evaluation, data used to monitor programs, communication materials, training sessions, program implementation decisions, personnel who are responsible for implementing wellness or OSH programs, and decision makers who influence program design or implementation; and perceived work factors that could be barriers that make it more difficult for employees to exercise or eat healthy food.

Surveys are self-administered using hard-copy forms. Survey respondents are generally the main OHBWC contact at the employer and the person most knowledgeable about OSH and wellness at the employer. The employer-level survey data will be linked to four years of retrospective WC claims data and four years of prospective WC claims to determine which organizational metrics are related to employer-level WC claim rates. Three different WWGP Employer Total WC rates will be used as dependent variables: WC claim rate per 100 employees, WC claim cost rate per 100 employees, and WC mean cost per claim.

Data Analysis

In preliminary analysis, the data will be examined for missing values and a merged de-identified data set will be created. All analyses will be conducted using SAS version 9.3 (SAS Institute, Inc., Cary, NC). Based on information collected during verification interviews, questions from the annual case study may be dropped from any statistical analyses or results will be interpreted accordingly. Specific subsequent analyses are described below.

Survey reliability and validity: Cronbach's alpha and the corrected item total correlation (ITC) will be used to assess proposed scale internal consistency for the OSH-Wellness Integration Module using data from all employers participating in the WWGP. An ITC of each item with its theoretical subscale should be at least 0.40 while Cronbach's alphas should be >0.6 to maintain items in proposed scales. The properties of the survey scales will be further examined using confirmatory factor analysis (CFA) before the final scales are determined.

Relationship of OSH-wellness integration to WC claims: The goal is to identify key integration practices that are most associated with reduced WC outcomes among participating WWGP employers. To determine the relationship between OSH, wellness, and OSH-wellness integration program elements and WC outcomes after controlling for covariates, multivariable Poisson regression will be used. The change in final survey scales over the four year study period will be compared to the change in WC claim rates for the same time period for each employer. The mean final survey scale values will also be compared to the mean WC claim rates for the same period.

The null hypothesis is that there will be no relationship between the survey-assessed wellness, OSH and OSH-wellness integration scales and WC claims. Covariates will include employer size, industry, prior loss experience, number and hours of OHBWC onsite consultation and participation in other OHBWC structured safety incentive programs (Safety Grants, Safety Council memberships, Drug-Free Safety Programs etc.). Significance will be assessed with tests of coefficients (t-tests) and overall model fit.

A16.B Project Time Schedule

Table A.16-1. Project Time Schedule

Activity	Time Schedule (Months After OMB Approval)
Conduct semi-structured economic interviews	1-6 months after OMB approval
Conduct annual case study verification interviews	1-6 months after OMB approval
Quality control and data reduction for economic interview data	7-9 months after OMB approval
Data reduction for annual case study data	7-9 months after OMB approval
Analysis of economic interview data	10-14 months after OMB approval
Analysis of annual case study data	10-14 months after OMB approval
Peer reviewed journal article presenting results of annual case study analyses	17-24 months after OMB approval
Submit report to OHBWC with results from economic interviews	17-20 months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no request for an expiration date display exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions being sought to the certification statement.

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