

Meeting Minutes
NIOSH Board of Scientific Counselors
395 E Street, SW
Washington, DC 20201
September 18, 2013

Introductions, Announcements, and Approval of Meeting Minutes

Dr. Bonnie Rogers, Chair, called the sixtieth meeting of the NIOSH Board of Scientific Counselors (BSC) to order at 8:41 am. Board members in attendance were Drs. David Bonauto, Kitty Gelberg, Robert Harrison, Daryl Hill, Clarion Johnson, Michael Kosnett, Michael Larranaga, John Mendeloff, James Ramsay, Corinne Peek-Asa, Jim Platner, and Ms. Jacqueline Nowell and Mr. William Kojola.

Dr. Rogers, BSC Chair, requested the members to declare potential conflict of interest related to the items listed in the agenda. No conflicts of interests were declared. A roll call and introductions among BSC members were conducted to confirm a quorum was achieved. BSC members Drs. Mendeloff and Gelberg participated by phone. John Decker provided safety announcements for the meeting as well as background on the Federal Advisory Committee Act (FACA).

The NIOSH Director (Dr. John Howard), the Deputy Director for Program (Dr. Margaret Kitt) and other NIOSH staff were present in person or via Envision. In-person NIOSH attendees were John Decker (Executive Secretary and Designated Federal Official), John Piacentino, Christine Branche, Matt Gillen, Alberto Garcia, Roger Rosa, and Joyce Rhoden.. Several additional NIOSH staff participated via Envision. In addition, several members of the public observed the BSC meeting via Live Meeting webcasting, with participation ranging from approximately 6 to 15 individuals.

Dr. Rogers requested approval of the previous meeting's Minutes from March 21, 2013. A correction was proposed to delete word "initiators" on the carbon nanotube section. After the recommendation was reviewed and discussed, and adopted, the BSC members voted unanimously in favor of accepting the Minutes.

NIOSH Director opening remarks

Dr. John Howard provided opening remarks, offering certificates of appreciation for BSC members completing their terms (Dr. Bob Harrison, Mr. William Kojola, Dr. Michael Kosnett, and Ms. Jacqueline Nowell). Dr. Howard also mentioned that Captain James Spahr is retiring from the Public Health Service and stepping down as the NIOSH Associate Director for Emergency Preparedness. Lisa Delaney will be the new Associate Director for Emergency Preparedness.

Budget

NIOSH is undergoing a budget exercise in the event a budget reduction of 5% for FY14 occurs as a result of sequestration. September 30th is the end of the FY13 year for budget issues.

NIOSH Center for Workers' Compensation will be a topic on the agenda today. Health and safety surveillance is an important issue, and NIOSH is attempting to save money on surveillance by

introducing electronic surveys rather than in-person surveys. NIOSH is participating in a CDC initiative to optimize agency surveillance systems by reducing redundancy in information collection.

OSHA has issued a Notice of Proposed Rulemaking (NPRM) to reduce the permissible exposure limit (PEL) for silica. NIOSH is preparing comments for OSHA on NPRM Occupational Exposure to Respirable Crystalline Silica.

The NIOSH Associate Director for Science Office (ADSO) is continuing to work on a NIOSH Data and Statistics Gateway (launched on September 18, 2013) to provide access to NIOSH research data. Through the webpage, NIOSH-generated public-use research datasets are available to the public for download. The Gateway provides convenient access to surveillance, statistics and other collections of NIOSH data. The Gateway will also help NIOSH meet several open-government and transparency-related goals the White House has established for agencies to make research information discoverable and accessible. Dr. Howard encouraged the attendees to visit and critique the website to improve its functionality.

NIOSH Total Worker Health (TWH) in Action newsletter has surpassed the 50,000 subscribers (more than the NIOSH E-news). NIOSH TWH newsletter has only been in existence for about 1-year, and membership has been expanding rapidly.

A new NIOSH Current Intelligence Bulletin will be available soon with new Immediately Dangerous to Life or health (IDLH) values. The NIOSH draft carcinogen policy, as well as an update to the heat-stress criteria document, will be released for public comment. Dr. Schulte from the NIOSH Education and Information Division indicated that the draft carcinogen policy, draft heat stress criteria document, and IDLH document are anticipated to be published in approximately one month.

Work Group Report: Structuring Labor-Management Participation in Research Partnerships

As indicated in the March 21, 2013 Minutes, the work group was charged with developing recommendations about structuring Labor-Management Participation in Research Partnerships. Work group members are Dr. Harrison (co-chair), Mr. Kojola (co-chair), Dr. Rogers, Dr. Peek-Asa, Dr. Larranaga, and Ms. Nowell.

Mr. Kojola and Dr. Harrison provided a summary of the work group report, describing each of the recommendations and the rationale for each. Six teleconferences of the work group were held. Note: The Minutes from the work group meetings are attached to these Minutes (see Appendix A). The work group heard presentations from NIOSH researchers, the NIOSH Institutional Review Board (IRB) chair, and Dr. James Platner on issues related to employee involvement in occupational safety and health research. The work group reviewed various relevant NIOSH documents and policy statements and received updates on the NIOSH study being conducted at Toyota.

The work group generated a draft document and provided the draft report to the full BSC prior to the BSC meeting. The BSC members deliberated over the draft report; the only change to the recommendations was to remove a word on bottom of Page 7 where the change would reflect the need

for NIOSH to address all studies rather than just “intervention” studies. A copy of the final report with the correction is attached to these Minutes (see Appendix B).

The BSC then voted on approval of the report. All BSC members present at the meeting voted in favor of the report.

BSC Letter to Dr. Howard

Before proceeding to the next agenda item, the BSC members discussed a draft letter about continuation of Education and Research Centers (ERC) and agriculture funding, with Dr. Kosnett leading the discussion. Note: See March 21, 2013 Minutes for more information on the Letter. The purpose of the letter is to provide Dr. Howard with additional documentation on the value and importance of the ERCs.

Dr. Harrison provided recommendations that instead of including only NIOSH, to include CDC/NIOSH. Dr. Larranga recommended to remove the words “believe and belief” as all these issues are already known or even a fact and the Board is already aware of the issues. Dr. Ramsay recommended mentioning that this is a unique and singular focus of funding for all these activities and that if this funding is not provided to the ERCs, no other programs will likely pick-up the funding, and they will have to be completely dropped. Dr. Rogers recommended adding a sentence about the number of publications (per year) that the ERC’s produce (estimated to be over 1,000 combined for the 18 ERC’s).

The BSC unanimously voted to approve the letter with the recommendations. Note: A copy of the final letter is attached to these Minutes (see Appendix C).

Hydraulic Fracturing: Opportunities for Research and Challenges in Protecting the Workforce

Max Kiefer, Director of the NIOSH Western States Office, provided an overview of the Oil & Gas Sector Program and the project to evaluate chemical exposures in this industry, including hydraulic fracturing. Mr. Kiefer indicated that the workforce in this industry is expanding with over 500,000 workers according to the Bureau of Labor Statistics (BLS). Most oil and gas extraction operations are conducted with 12-hr shifts with continuous 24 hour per day processes. Over half of the companies in this industry have less than 100 employees. The fatality rates in the oil and gas extraction industry are about six to seven times the rates of other industries. The NIOSH team is comprised of a multi-disciplinary group to help determine priority safety and health issues, and guide and conduct research. Worksite operations, processes, and chemicals used in the industry suggest that workers have potential risks for exposures to multiple chemical hazards. Some of the chemical risks include silica, diesel emissions, components of fracturing fluids, hydrocarbons, hydrogen sulfide, acids, biocides, polycyclic aromatic hydrocarbons, and metals. Mr. Kiefer noted that hydraulic fracturing is just one of several activities in a post-drilling process known as “completions”. There are several other steps where NIOSH has an interest, and current exposure assessment focus is on “flowback” operations, which is conducted after completion of hydraulic fracturing.

Mr. Kiefer discussed the multiple points of dust generation during the hydraulic fracturing process, the primary contributors to worker exposure to respirable crystalline silica, and that controls have been recommended to address each point of dust generation. NIOSH is currently focused on evaluating the effectiveness of silica dust controls, including a NIOSH developed and patent-pending, control. Additionally, NIOSH is evaluating worker exposure to volatile organic compounds (VOC), dermal and biological monitoring for various petroleum products, and conducting toxicological research. The NIOSH team is also working at expanding partnerships with industry and revising the 1983 NIOSH document "Comprehensive Safety Recommendations for Land-Based Oil and Gas Well Drilling."

Mr. Kiefer asked the BSC members suggestions for communicating new findings of hazards in this industry and also for presenting findings where NIOSH already has conclusive scientific evidence of a hazard but has not yet published a peer-reviewed article.

Dr. Rogers opened the presentation for Board Discussion. Dr. Platner recommended talking to enforcement officers who have experience inspecting drilling operations and reviewing required Safety and Environmental Management Systems (SEMS), such as the US. Department of the Interior and the Bureau of Safety and Environmental Enforcement (BSEE). Mr. Kojola liked the OSHA-NIOSH Hazard Alert and emphasized that NIOSH should publish and disseminate research findings in a timely fashion (perhaps even before the information is published in journals). Dr. Kosnett asked if NIOSH had an estimate of the percentage of fracturing operations where employees had proper protection; Mr. Kiefer mentioned that it would be speculative on his part to answer this question as this is such a rapidly expanding industry and it would be difficult to estimate these numbers. Dr. Kosnett asked if OSHA had pending citations on these operations, and Mr. Kiefer said he was aware of a few, but asking OSHA directly would provide more definitive information. Dr. Kosnett also mentioned that he would encourage publicizing new findings in venues such as the Society of Toxicology meeting as means to promote dissemination of the information. Dr. Kosnett also mentioned that NIOSH should try to reach professional audiences and compile publications on this topic.

Dr. Nowell asked if NIOSH was working with the Mountain and Plains (MAP) Education and Research Center (ERC). Mr. Kiefer responded that he works closely with the ERC on this and other occupational safety and health issues. Dr. Nowell also recommended having the information disseminated to safety directors of International Unions. Dr. Peek-Asa mentioned that industries that have successfully disseminated research findings are those that get the workforce involved in the process. Dr. Peek-Asa also recommended publication in peer-reviewed professional and trade journals to improve dissemination. Dr. Bonauto agreed with publication in trade journals and asked if NIOSH was aware of the responsible party for the contractual conditions of these operations. Dr. Peek-Asa also reminded NIOSH of the importance to continue injury prevention activities, as the fatality rates are high and the remote nature of these operations complicate care for injured workers. Dr. Mendeloff indicated that he was aware that OSHA has conducted a number of inspections in this industry and recommended checking the database for these inspections.

Dr. Harrison suggested that it would be important to think of ways where NIOSH could establish and

expand partnerships. For example, California has a work group to examine environmental risk, as hydraulic fracturing is expected to expand in California in the coming years. Dr. Johnson recommended contacting the Society of Petroleum to present these findings. Dr. Platner reminded everyone that much of this work is construction-related, and most of the construction work is unionized (at least in Pennsylvania). Dr. Kosnett indicated that sometimes contractors that sub-contract incur overarching liability. General contractors need to be made aware of this issue as it could provide incentives for proactive measures to ensure a safer workplace.

NIOSH Safe-Skilled-Ready Workforce Initiative

Dr. Paul Schulte and Rebecca Guerin discussed the new NIOSH Safe-Skilled Ready Workforce Initiative. The presentation was well-received and the BSC members showed much interest in the topic and materials presented. A skilled and healthy workforce is clearly desirable and needed. The Safe-Skilled-Ready workforce initiative promotes workplace safety and health as a missing life skill, and it complements existing work readiness skills, frameworks, and training programs.

This initiative promotes generalizable and transferable workplace safety and health skills (the eight core competencies). These include the ability to:

Recognize that, while work has benefits, all workers can be injured, become sick, or even be killed on the job. Workers need to know how workplace risks can affect their lives and their families.

Recognize that work-related injuries and illnesses are predictable and can be prevented.

Identify hazards at work and predict how workers can be injured or made sick.

Recognize how to prevent injury and illness. Describe the best ways to address workplace hazards and apply these concepts to specific workplace problems.

Identify emergencies at work and decide on the best ways to address them.

Recognize employer and worker rights and responsibilities that play a role in safe and healthy work.

Find resources that help keep workers safe and healthy on the job.

Demonstrate how workers can communicate with others—including people in authority roles—to ask questions or report problems or concerns when they feel unsafe or threatened.

The initiative considers the total workforce and approaches the total, future workforce focusing on educating young and new workers. It also recognizes that employers are responsible for providing a safe and healthy workplace. The initiative promotes the idea that everyone should have basic skills to help them stay safe and healthy at work and to contribute to a safe, healthy and productive workplace.

The initiative will promote the core competencies through three pathways: 1) Education (e.g. through community colleges and middle and high school curricula and through the foundational workplace safety and health curriculum from NIOSH, Youth@Work-Talking Safety); 2) Business and labor (e.g. through existing apprenticeship, on-the-job-training, and other work-readiness/skills training initiatives);

and 3) Health (e.g. through coordinated school health programs and primary care providers and pediatricians).

Dr. Larranaga mentioned that his university can use this information and include it as part of training curricula. Dr. Larranaga found that parents and grandparents of the students also become engaged in these types of activities. Dr. Platner recommended disseminating these excellent materials to high school Co-op coordinators to improve their awareness of broader occupational safety and health issues. This could supplement Co-op coordinator training on hazardous child labor restrictions that is mandatory in some states before they can refer students to co-op work sites. They would also be of value to pre-apprenticeship programs.

Ms. Nowell recommended approaching the Child Labor Coalition (CLC) and the National Consumers League (NCL) as good organizations to promote the NIOSH core competencies. Ms. Nowell also mentioned that it can be difficult to reach people that are already part of the workforce. Ms. Nowell was curious about how NIOSH was planning to communicate with these groups. Ms. Nowell also urged NIOSH to think about community organizations. Ms. Nowell is a proponent of including these workplace safety and health competencies in English as a Second Language (ESL) curricula. Dr. Kosnett echoed what Ms. Nowell's sentiments recommended including these materials to groups that focus on immigrants entering the workforce.

Dr. Ramsay encouraged the team to look back at NIOSH's "Steps to a Healthier U.S. Workforce" initiative. Dr. Hill offered to share with NIOSH and the BSC members case studies from his company. Mr. Kojola mentioned that this initiative has the potential to change the workplace. Mr. Kojola also mentioned that it is necessary to have skilled workers, but it is not sufficient only to change the conditions of the workplace. It is critical to obtain buy-in from employers to make this Initiative successful. Dr. Rogers said that this is a great effort and it is long overdue. Dr. Rogers also recommended working with literacy councils as a means to disseminate/implement the NIOSH workplace safety and health competencies.

Afternoon session called to order at 1:10 and a roll call was conducted for BSC members on the phone.

Strategy, Plans, and Timeline to Evaluate Second Decade of NORA

Dr. Sarah Felknor, NIOSH Associate Director, gave a presentation entitled "Planning for the NORA 2016 Evaluation". The purpose of this evaluation is to assess the investment, approach, and impact of NORA2006-2016. Additional purposes were to obtain input from different stakeholder groups as to the strengths and weaknesses of NORA2006-2016, and to recognize that NORA1996-2006 and NORA2006-2016 had different origins and were responsive to different challenges.

The scope of this evaluation was to obtain the big picture perspective, including both intramural and extramural, of all NORA – funded activities. This evaluation was also designed to answer three fundamental questions:

1. What did NIOSH do during NORA2006-2016?
2. How well did we do it?
3. What was the impact?

A concurrent evaluation of the management and coordination of the second decade of NORA will be implemented to assess the effectiveness of the organizational structure that managed the decade of activities.

The intended audiences for this evaluation are funding agencies, stakeholder groups, the NIOSH intramural and extramural research community, policy making groups, other occupational safety and health organizations, and thought leaders. The products of this decade evaluation will include comprehensive final printed reports, electronic information for easy download and quick messaging, bibliometrics of the second decade of NORA, impact stories, and other evidence of impact; Internal infrastructure for lasting performance evaluation across NIOSH. Dr. Felknor indicated that the final report(s) should be expected at the end of April, 2015.

Dr. Mendeloff asked how the work group is defining NORA, and which activities are not being undertaken by this evaluation. Dr. Felknor indicated that for the purposes of this evaluation, NORA is defined as any activity (intramural and extramural) that was funded with NORA funds. Dr. Harrison also recommended that NIOSH should include different success stories in short informative pieces, something similar to a “30-second elevator conversation story”.

Dr. Peek-Asa agreed that success stories will help. Dr. Peek-Asa asked about the 3 domains (Sector Councils, Partnerships, and Research), as it appeared to be an apple to oranges comparison. Dr. Peek-Asa asked about the impact of a partnership, for example, and how does that differ from any other research activity. Dr. Felknor indicated that the domains for each of the three strata (Councils, Partnerships and Research) will be well defined and that for each domain, they have drafted specific evaluation questions to better describe what is being evaluated.

The second decade review will include an assessment of how NORA was managed within the Institute. The evaluation will include recommendations for the next decade based on lessons learned, but will not include a plan for NORA 2017 - 2027. Dr. Rogers asked if there is already an idea on how the two decades of NORA will be compared and how the third decade will be shaped. Dr. Felknor responded that the two decades were designed to address different issues and had different goals at different times in history which would preclude a one-to-one comparison. Any comparison will also be limited by the type of evaluation data that resulted from the NORA 2006 – 2016 review.

Dr. Harrison asked whether the evaluation will have a comparison of funding vs. level of success rate and the funding scores. Dr. Harrison mentioned that it would be good to obtain this qualitative piece of information. Dr. Felknor reported that NIOSH increased the success rate of extramural grants in FY12 to 18% from 14% in FY11. Including assessment of the external research funding levels over the 2006 – 2016 decade would provide useful context to any financial assessment of NORA 2006 – 2016. Parallel data of intramural and extramural funding and success rates will be evaluated by sector and cross sector

program areas.

Dr. Rogers mentioned that when looking at the Sectors, NIOSH needs to be careful in making comparisons. One Sector may not have received a level of funding due to a lack of high quality applications, so a Sector to Sector comparison might not be appropriate. Dr. Platner suggested that the goal of this evaluation should be to help garner interest and support for NIOSH research and the NORA, and it is not quite clear how the evaluation plan will address that goal. Dr. Felknor mentioned that the NORA 2006 – 2016 evaluation work group will consider this as the evaluation plans are finalized in the next several weeks.

NIOSH Center for Workers' Compensation Studies (CWCS)

Dr. Wurzelbacher from NIOSH gave an overview of the CWCS as a new NIOSH center developed to maximize the use of workers' compensation (WC) data for prevention purposes. The presentation was well received by the BSC, and several board members provided input when asked for ideas for research priorities and ways to increase the impact of the center. These responses are summarized below.

Dr. Platner suggested that the center could examine systematically those work-related injuries and illnesses that are typically not covered by WC (such as longer term illnesses). Dr. Howard responded that this is not a primary goal of the CWCS, but that NIOSH researchers in the Economics program and other external researchers have been focusing on this issue. As a recent example, a NIOSH researcher is being detailed to the Social Security Administration (SSA) to study how work-related injury and illness costs may be shared by other entities.

Dr. Mendeloff suggested that a first step for the center should be a quality control study of available WC data to understand what data elements are useful for prevention purposes and which are most reported by partners. Dr. Wurzelbacher agreed that an initial goal is to understand the limits of the data, and that the scope and quality of data will vary by each partner. A primer for WC analyses is being developed by NIOSH to help researchers understand overall WC data complexities and limitations.

Dr. Harrison mentioned that California has a recent example of how WC data can be useful for surveillance purposes. Valley Fever WC cases were noticed among construction workers by a NIOSH EIS officer and reported to the State Department of Health.

Dr. Nowell asked how NIOSH gains access to WC data. Dr. Wurzelbacher responded that there is no pattern other than persistence and approaching partners to develop true collaborations rather than just asking for data. Dr. Nowell asked if NIOSH would share the data with a Union. Dr. Wurzelbacher responded that the output analyses of the data would be shared.

Mr. Kojola stressed the importance of CWCS Strategic Goal 2, especially the activity of "evaluating leading indicators associated with lower workers' compensation claim frequency and severity to identify evidence-based safety and health programs, practices, and policies." Mr. Kojola commented that this is one way to identify validated and relevant indicators, and this will help to understand what's driving injuries and illnesses in a different fashion than BLS data.

Dr. Kosnett was supportive that industrial hygiene (IH) exposure and WC claims data would be examined by the CWCS and other researchers. Dr. Kosnett commented that he would like to see the extent of IH consultations by WC carriers and how this could affect WC claims. Dr. Kosnett also suggested that it would be useful to determine if consultations with toxicologists and board certified occupational medicine providers would affect WC claim frequency and severity.

Dr. Bonauto stressed that it is important to understand how underwriters view WC data differently from loss prevention and safety professionals. Dr. Howard remarked that WC data can be useful for developing predictive analytics to anticipate future injury-illness frequency and severity by cause and industry. Such analytics can be useful for both underwriting and loss prevention purposes.

Concluding Remarks

Dr. Rogers identified three potential items for the next BSC meeting, including a review of the NIOSH motor vehicle safety program, intramural and extramural integration, and surveillance/electronic health records. Dr. Rogers asked BSC members to send items for future meetings via email. Dr. Nowell recommended possibly placing the topic of ergonomics back on the agenda.

Appendix A – Work Group Meeting Minutes: Structuring Labor-Management Participation in Research Partnerships, April 1, 2013, May 9, 2013, May 23, 2013, June 13, 2013, August 12, 2013, and September 30, 2013

MINUTES

April 1, 2013, 10:00 am – 11:30 am

Work Group: Board of Scientific Counselors

National Institute for Occupational Safety and Health

Structuring Labor-Management Participation in Research Partnerships

Charge to BSC & Work Group Procedures

The meeting was convened at 10:00 am, with the following NIOSH Board of Scientific Counselors present: Bonnie Rogers (BSC Chair), Bill Kojola, Corinne Peek-Asa, Jacqueline Nowell, Michael Larranaga, Robert Harrison. NIOSH staff present included John Decker, Roger Rosa, Gayle DeBord, Greg Lotz, Brian Lowe, Mark Toraason, Naomi Swanson. John Decker served as Designated Federal Official for the meeting. This work group was formed as a result of deliberation and a vote of the BSC on March 21, 2013.

John Decker provided an overview of the requirements and procedures for work groups under the Federal Advisory Committee Act. Bonnie Rogers reviewed the charge to the BSC work group, which had been discussed at the March 21, 2013 BSC meeting. Since the BSC meeting, the charge to the work group was clarified by Dr. Howard with the addition of a sentence “In addition, the NIOSH Director would welcome any recommendations that would further enhance the scientific quality of the planned intervention study while ensuring that worker participation in the study is entirely voluntary and that the results of the study pertaining to individual workers remain confidential.” The work group discussed the charge.

The work group decided that Bill Kojola and Robert Harrison would serve as co-chairs for the work group. The work group decided that Bill Kojola and Robert Harrison would serve as co-chairs for the work group. Bonnie Rogers will be a member of the work group, and as BSC chair, will work with the co-chairs in an advisory capacity.

NIOSH Tripartite Policy

John Decker and Gayle DeBord provided an overview of the NIOSH policy, titled “Informing and Engaging Affected Parties in Field Studies: Tripartite Review,” dated October 2010. A short discussion of the work group followed, and Gayle DeBord answered questions. A copy of the policy was provided to the work group prior to the meeting.

Case Study: Overview of Musculoskeletal Research Study

Brian Lowe gave a PowerPoint presentation on the musculoskeletal research study. The presentation was followed by discussion and questions from the work group. A copy of the PowerPoint slides and the NORA protocol was provided to the work group.

Schedule/Topics for Future Meetings

The work group discussed potential future discussion topics that would facilitate work group understanding and discussion of the topic. These following potential topics were considered:

Convening a work group discussion with experts in participatory community research, including the experiences of researchers who have conducted such research. Discussion could include considerations of how the research is initiated, for instance, whether it is community-initiated, researcher-initiated, etc.

Follow-up and responsibilities after the research is completed and the researchers are no longer on-site.

Role and function of Data Safety Monitoring Boards (DSMBs)

Other organizations' procedures, including CPWR and those of unions such as the UAW.

Research ethics

Wrap-up, Schedule for Future Meetings

The work group decided that Bonnie Rogers and the co-chairs would begin prioritizing agenda topics for future meetings, determine a time-line for the work group activity, and determine the work group schedule. The co-chairs are planning to get back with the rest of the work group within the next week or so. John Decker will send the work group NIOSH's response to the UAW comments.

MINUTES

**Work Group: Board of Scientific Counselors
National Institute for Occupational Safety and Health
Structuring Labor-Management Participation in Research Partnerships
May 9, 2013, 11:00 am – 12:15 pm ET**

Participants:

BSC Members: Bill Kojola (Work Group Co-Chair), Bonnie Rogers (BSC Chair), Corinne Peek-Asa, and Michael Larranaga

NIOSH: John Decker, Roger Rosa, Greg Lotz, Doug Trout

Designated Federal Official: John Decker

Toyota Musculoskeletal Project Update

Greg Lotz indicated that NIOSH would begin recruiting for participants within the next 1-2 weeks, and the project would follow the design as previously discussed with the work group, involving four study arms on 2 assembly lines and 2 shifts. Workers/potential study participants will be given an informational flyer, and briefings on the study will be held for workers. Workers also will be given consent forms to take home and consider overnight before making a decision to participate. The study will be conducted over a 10-month period, and NIOSH staff will be conducting the data collection and analysis. Each arm will have 25 participants; the number of employees/line was not available. Exceeding the pre-designated participation stated in the protocol would be an Institutional Review Board (IRB) issue and would require an amendment to the protocol.

As a general matter, Doug Trout indicated that NIOSH provides workers an opportunity to discuss and ask questions about a research project away from a group setting; a small percentage of workers would typically utilize this avenue of communication. Discussion usually occurs on the company premises and on company time, but it probably has occurred off premises and off-hours in isolated instances. It was noted that workers can also initiate a phone call to NIOSH staff for private questions.

Review of Consent Forms

Doug Trout, the co-chair of the NIOSH IRB, provided perspective on proposed revisions/updates to NIOSH consent forms, explaining that consent is really more than the form itself, but is a process for communication between the study team and research subjects. The draft revised consent form has been simplified compared to the current template; the consensus is that consent forms have become overly complex in recent years. The draft NIOSH consent form will require additional internal reviews and Director's approval before it will be finalized, which could occur later this year. BSC work group members had some suggestions about enhancing some of the questions on the new consent form template. There also was discussion about whether the IRB considers harms other than physical harms (for instance, psychological harm or economic harm). Doug Trout indicated that the NIOSH IRB routinely considers other types of harms, for instance, whether medical information could impact health insurance, and whether workers would be worrying about test results. It was also explained that NIOSH has one IRB that reviews all types of studies conducted by NIOSH. The NIOSH IRB includes representation from various disciplines, but the IRB also has an ability to call on outside expertise when

needed. There was a comment that IRBs (outside of NIOSH) that don't review many occupational safety and health protocol reviews sometimes have trouble assessing risks. A suggestion was that NIOSH might consider disseminating guidance in this area, although it was unclear what this might entail. It was pointed out that the NIOSH OD conducted a benchmarking exercise of the NIOSH IRB within the past couple years; a copy of this report would be identified and sent to the work group.

Potential “back end” recommendations for NIOSH musculoskeletal study

Proposed back-end recommendation could involve a NIOSH “hotline” and a post-study survey among workers who participated in the study. Kojola indicated that Bonnie Rogers, who had to leave the call early, had some ideas about possible questions that could be included as part of a post-study survey. Some questions could include aspects of the project plan items (see questions at end of this report). Greg Lotz indicated that the project officers had discussed the possibility of conducting a post-study survey among participants, and he felt that an addition would be feasible and meaningful. It was noted that the NIOSH health hazard evaluation program has a follow-back survey, and some of the questions might be relevant for a follow-up survey for research projects. A copy of the HHE program survey will be obtained and sent to the work group. Regarding an 800 number, it was noted that NIOSH no longer has a 800-number, and it has been replaced by a CDC-info number that has been plagued with contractor-related performance problems in the past year or so.

Initial Discussion on Mechanisms to End Studies Early.

Doug Trout commented that NIOSH does not conduct studies involving treatment, so NIOSH studies do not typically involve benefits/risks in the same way of other studies involving treatment-related research. NIOSH has a formal program for adverse events—when anything outside the protocol occurs, the project officers need to almost immediately contact the IRB office. The NIOSH IRB has a formal process for categorizing and analyzing adverse events or unanticipated risks to subjects. For any given activity within NIOSH the study team is responsible for identifying and reporting (to the IRB) adverse events; reporting of events does not typically occur from the study subjects. There is not a formal process for systematically identifying adverse events while the study is in progress. This could be a topic for the IRB to discuss.

Wrap-up, Future Meeting

The next work group meetings will be on May 23 and June 6 at 11:00 am ET.

Action Items

John Decker will send the NIOSH IRB Benchmarking Report and the Health Hazard Evaluation post survey questionnaire to the work group.

Bonnie Rogers will provide potential questions that might be considered for a post-research survey of workers.

Additional future discussions:

Contents of a post-research study questionnaire among workers

Discussion of IRB processes to identify adverse events

IRB composition/social and economic harm

The co-chairs will more fully develop an agenda for future work group meetings.

Proposed Plan from Co-Chairs: Use the Toyota study as an opportunity to build in process evaluation with focus on workers. We won't critique or focus on study design per se, but use this as an opportunity to improve our understanding of how we can best engage workers in NIOSH studies. The information learned from this study can help NIOSH improve their guidelines for joint labor/management participation protocols and procedures for researchers. Possible issues to focus on:

What are the practical, effective and feasible methods to ensure worker involvement and get the study information out to those who can use it?

What worked most effectively in the study to enhance and ensure worker participation?

What was understood by the workers about study design?

Was there any coercion involved?

What are the mechanisms for protecting workers against potential adverse social/economic consequences?

What benefits did workers see in being involved?

Why did they participate in the study?

Did they understand the results (and what did they understand)?

What action would workers take based on the study?

Did anything actually change on the shop floor as a result of the study?

What methods were implemented to monitor the findings and possibly end the study before the end?

MINUTES

Work Group: Board of Scientific Counselors

National Institute for Occupational Safety and Health

Structuring Labor-Management Participation in Research Partnerships

May 23, 2013, 11:00 am – 12:15 pm ET

Introductions: BSC members in attendance included Bill Kojola, Corinne Peek-Asa, and Jackie Nowell. NIOSH staff present included John Decker (Designated Federal Official), Roger Rosa, Greg Lotz, and Mark Toraason.

Toyota Study Update

Greg Lotz provided an update on the Toyota study. Brian Lowe, the Project Officer, made the initial recruitment and consent of subjects last week. Brian briefed the team leaders for the four assembly line groups. The Toyota team leaders invited the workers to a briefing that Brian held as a group during their break time. Workers were asked to come back the next day if they wanted to participate. There was variation in attendance; of those attended, participation ranged from $\frac{1}{2}$ to $\frac{3}{4}$ of group (as low as 10 for the control to 19 for the tool support group). Greg Lotz explained that even if NIOSH falls short of the 25 targeted, they will still proceed, but statistical power will be diminished. Each arm of the study will continue with their normal routine for 3 months to assess symptoms before the intervention begins. Question: Why did workers refuse? Project officer did not have a good sense of the reasons, particularly for workers who did not come to the meeting. Workers did not have a lot questions—they either signed up or not. Management representatives (safety team leader) were present during the work briefings. Does NIOSH have any way to find out barriers to participation? Greg Lotz indicated NIOSH don't have a structured way, but DART is discussing ways to get at this question. Comment: It would be useful for the BSC work group to make recommendations on ways to overcome barriers. Question: Is it typical that these meetings are done on break time? Greg Lotz indicated this is the way Toyota requested it be handled, possibly to avoid impacting the assembly line. The remainder of the study will all be done on paid time. What percent of total worker population could have showed up? There are about 30 potential individuals; NIOSH got 15-26 of those who showed up for the briefing. So, with a target of 25, NIOSH needs most workers to participate. Those workers who are not participants in the study will not be using the intervention, i.e. will not use the intervention tool.

Follow-up, Toyota Survey

HHE Followback Surveys

The work group discussed the follow-up surveys from the HHE program, to help develop ideas about a similar type of back-end survey for research projects, including potentially the Toyota study. The HHE follow-back surveys involve a simple series of questions that apply to that particular HHE. Some questions are in the realm of what the BSC work group discussed previously: Did people think their participation was voluntary? Did they feel the study was valuable? Were there any changes in the workplace? Did employees feel the information they provided was held in confidence? Did NIOSH keep you well informed? During the site visit, were you able to fully express the issues as you saw them?

When work group formulates its recommendations, their recommendations will be focused on broader issue on post-study follow-up with workers. For the Toyota project, Greg Lotz indicated that the project officer is amenable to pursuing such ideas.

IRB Benchmarking

The work group discussed the internal NIOSH benchmarking Executive Summary. John Decker discussed why the full report was not provided. The applicability of FWA (Federal-Wide Assurance) was discussed. Toyota is not considered to be a research partner, so FWA was not done for the Toyota project.

The benchmarking report was originally pulled into the BSC work group sphere because it relates to worker participation. Mark Toraason indicated that the IRB does not just examine physical hazards, but also whether there any potential economic/social interactions. IRB does go beyond physical harm. It considers confidentiality, including whether participation is voluntary. Most high risk studies are concerned with physical harm. Occasionally, studies inquire about illegal drug use. The proportion of workforce that is unionized is dropping, as NIOSH finds itself trying to conduct research, the study sites will be increasingly be non-unioned.

Existing Mechanisms To Protect Worker's Against Potential Adverse Social/Economic Consequences

What are the existing mechanisms to protect workers? What are the mechanisms? The context for the BSC work group related to potential adverse actions taken by the employer (not adverse actions like loss of confidentiality). NIOSH hasn't focused on the possibility that the employer will take actions against the employee, given that the employer has voluntarily allowed NIOSH to enter the premises and conduct research. If such adverse actions occur, NIOSH doesn't have real authority over the employer; NIOSH doesn't have a way to take actions if such an event occurred. In these research studies, you have a partner with the employer assumed to be voluntarily cooperating. It is assumed, more likely than not, that the employer will not take action against worker. Sometimes, NIOSH conducts studies off-site to determine if the employer does not want to participate. An example involves research in the dry cleaning industry, where employees were biomonitoring off site. Employer might not even know if workers are participating in the study. What are the remedies for a worker in a non-represented work place? How do we determine if there was an adverse reaction if they participation? Problem: There is no current mechanism to determine this. Example: In-vehicle monitoring systems for drivers; what happens if employers know about poor driving behaviors and the information adversely impacts the employee (employer take adverse actions). NIOSH/researchers do not have recourse with the employers in such circumstances. In the case of acrylamide research, researchers suspected that those workers who had high exposures were later noted to be no longer occupying those same job positions during later visits to the companies. It was not known whether the employees were let-go or moved to another part of the company.

Additional Issues For WG To Examine

BSC members are to provide agenda items to Bill Kojola for future meetings. Next meeting is June 6 at 11am ET.

Wrap-up, Future Meetings

Next meeting is June 6 at 11am ET.

The work group will schedule two more calls beyond June 6.

Proposed Plan from Co-Chairs: Use the Toyota study as an opportunity to build in process evaluation with focus on workers. We won't critique or focus on study design per se, but use this as an opportunity to improve our understanding of how we can best engage workers in NIOSH studies. The information learned from this study can help NIOSH improve their guidelines for joint labor/management participation protocols and procedures for researchers. Possible issues to focus on:

What are the practical, effective and feasible methods to ensure worker involvement and get the study information out to those who can use it?

What worked most effectively in the study to enhance and ensure worker participation?

What was understood by the workers about study design?

Was there any coercion involved?

What are the mechanisms for protecting workers against potential adverse social/economic consequences?

What benefits did workers see in being involved?

Why did they participate in the study?

Did they understand the results (and what did they understand)?

What action would workers take based on the study?

Did anything actually change on the shop floor as a result of the study?

What methods were implemented to monitor the findings and possibly end the study before the end?

MINUTES

Work Group: Board of Scientific Counselors National Institute for Occupational Safety and Health Structuring Labor-Management Participation in Research Partnerships June 13, 2013, 11:00 am – 12:00 pm ET

Toyota study update

Greg Lotz provided an update on the Toyota study. There were a few more enrollees, totaling about 60 now. Initial surveys have been largely gathered. Employees place their surveys into a locked box that only NIOSH can open. There is a possibility that there may be a few more enrollees. NIOSH is a bit short in terms of number of enrollees originally planned for study. Regarding the overall process, the NIOSH researchers would have liked a bit more time to pitch the study (It was done during workers' break, and it may not have reached all employees). Employees will be authorized to complete surveys on work time, but the initial recruitment was done on break time, probably not more than 10-15 minutes. Anecdotal observation: Employees did not seem worried about management watching them.

Non-union workplaces, safety committees, and the National Labor Relations Act

Employers may set up safety committees to deal with safety and health issues, and under certain circumstances, it can act as a labor organization. In this circumstance, the NLR could come into effect, and the employer in this instance cannot dominate the committees and select members. Cautionary note: In some circumstances, NIOSH may need to seek legal counsel to ensure it is not creating a process that might violate NLR.

Other issues to examine

A question is whether there should/need to be a Memorandum of Understanding prior to initiating research. Currently IRB often looks at less formal Letters of Agreement, but there was a suggestion that the details of what should be included might be better specified by NIOSH. BSC might suggest a general framework or broad checklist to guide the content of Letters of Agreement or Memorandums of Understanding. Memorandum of Understandings are usually more general in nature, whereas the Letter of Agreement typically is a bit more detailed about the specific actions to be taken in the study.

Tripartite Policy mentions a worker notification policy related to notifying workers about their individual results. The worker notification policy was recently revised; John Decker will send it out to the BSC. Another policy is about relaying the overall study results to study participants; this policy will be identified and sent out as well.

Recommendations and report – initial discussion

Bill Kojola will review the notes and minutes of previous meetings. He will start drafting an outline along with draft recommendations.

Timelines for completing our assignment, Future Calls

Most subsequent work will be done via email. A work group meeting will be reserved for August 12, but John Decker will initially send an inquiry to the work group to confirm the date.

Participants:

BSC Members: Bill Kojola and Bob Harrison (Work Group Co-Chairs), Michael Larranaga

NIOSH: John Decker, Greg Lotz, Mark Toraason

Designated Federal Official: John Decker

Proposed Plan from Co-Chairs: Use the Toyota study as an opportunity to build in process evaluation with focus on workers. We won't critique or focus on study design per se, but use this as an opportunity to improve our understanding of how we can best engage workers in NIOSH studies. The information learned from this study can help NIOSH improve their guidelines for joint labor/management participation protocols and procedures for researchers. Possible issues to focus on:

What are the practical, effective and feasible methods to ensure worker involvement and get the study information out to those who can use it?

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Was there any coercion involved?

What are the mechanisms for protecting workers against potential adverse social/economic consequences?

What benefits did workers see in being involved?

Why did they participate in the study?

Did they understand the results (and what did they understand)?

What action would workers take based on the study?

Did anything actually change on the shop floor as a result of the study?

What methods were implemented to monitor the findings and possibly end the study before the end?

MINUTES
Board of Scientific Counselors, Work Group
National Institute for Occupational Safety and Health
Structuring Labor-Management Participation in Research Partnerships
August 12, 2013, 11:00 am – 12:15 pm ET

Minutes

Introductions

Individuals present: Bill Kojola, Bob Harrison, Bonnie Rogers, Michael Larranaga, John Decker (Designated Federal Official), Joyce Rhoden (NIOSH staff).

Review of draft work group report, discussion of outstanding items

The work group reviewed the comments from Bonnie Rogers and Corinne Peek-Asa. Those comments were highlighted in yellow in the revised draft sent to the work group by Bill Kojola (3rd Word document above). The specific draft recommendations that were discussed are also repeated again in bolded text below:

“NIOSH should encourage investigators to use worker-guided or worker-participatory research methods, which would entail some pre-study integration of representative workers and/or employers prior to finalization of study protocols. These approaches can help identify issues prior to study implementation so that they can be addressed in the design phase.”

Comments: Bonnie Rogers & Bob Harrison expressed concerns that the recommendation would be difficult to implement for all research. In addition, recommendations made not be practical or feasible or in line with the IRB.

Resolution: Bill Kojola will modify recommendation, to add a qualifier to recommend participatory research if the researcher thinks it is appropriate, then participatory research should be considered. Bill will send revised draft around.

“NIOSH should explore approaches and develop a mechanism for identifying situations where an adverse consequence to an employee has occurred. NIOSH should also identify the options that may be available for employees to initiate actions to protect themselves in circumstances where they believe they have experienced an adverse consequence and to provide that information to the employee.”

Comments: NIOSH might not have many options on what it can do if this situation occurred. In union setting, this sort of problem would be resolved through the grievance procedures.

Resolution: Delete Recommendation.

“NIOSH should consider seeking legal counsel before it engages in field/intervention studies where employee participation and involvement is sought so that NIOSH does not encourage the formation or employer domination of safety and health committees that may violate Section 8(a)(2) of the NLRA.”

Comments: Lawyers might tie up the process and delay research. This is clearly a legal issue that could occur in non-union settings.

Resolution: Make the recommendation oriented more from an educational standpoint for NIOSH staff than legal standpoint. Bill Kojola will modify and send revised draft.

“For intervention studies, including randomized control trial study designs, NIOSH should consider creating a “data and safety monitoring board” patterned after those established by NIH in clinical research. In order to ensure the safety of participants, these boards would examine interim study data for the purpose of assessing benefits and risks to participation workers and take necessary action to modify, terminate, or continue the study.”

Comments: It was unclear whether a DSMB patterned after NIH would be appropriate for NIOSH. It would nonetheless be useful for NIOSH to develop some policies around randomized controlled trials, that is, to include provision to end a study early if necessary.

Resolution: Change “data safety monitoring board” to a more generalized “monitoring mechanism” for NIOSH to evaluate interim study data to discontinue a study. Bob Harrison will revise the draft. John Decker will check with Mark Toraason to confirm if there are any current NIOSH procedures.

“NIOSH should consider developing some general criteria or guidelines for minimum elements that must be contained in a letter of agreement beyond that of an employer demonstrating its good intention to participate in the study. The letter might contain some additional elements, such as stating that employee participation will be voluntary, employees can withdraw from participation at any time during the study without reprisal, and that confidentiality will be maintained. Other issues specific to the particular study being conducted could also be included in the letter.”

Comments: Participants liked the current language. No changes were proposed.

Plans to finalize draft

Timeline for completing draft report: Bill Kojola will send out a revised draft on Tuesday AM (August 13). Work group needs to respond to revised draft by close of business on Wednesday, August 14.

Distribution of draft report to the full BSC: A draft report will be sent out to the full BSC as soon as it is ready (but by the end of August at the latest). Bob Harrison will work with John Decker on any loose ends between now and end of August.

Next work group meeting: Another work group call will be needed prior to the September 18 BSC meeting to resolve any comments from the full BSC. The work group call will be on Monday, September 9, 2013 at 11:00 am ET.

Finalization of draft: The work group’s desire is to resolve the full BSC comments to the extent possible prior to September 18, 2013 BSC meeting, so that the report can be voted and accepted by the BSC without edits.

**Minutes
Board of Scientific Counselors, Work Group
National Institute for Occupational Safety and Health
Structuring Labor-Management Participation in Research Partnerships
September 9, 2013, 11:00 am – 12:15 pm ET**

Agenda

Introductions

Bob Harrison, Bill Kojola, Michael Larranaga, Bonnie Rogers, and Corrine Peek-Asa were in attendance. John Decker served as designated federal official.

Review of comments from BSC; finalize draft

Plan: BSC will be provided a copy of the draft report. BSC members will vote on the document at the September 18 BSC meeting.

BSC member comments were received from Carol Rice and James Platner.

Carol Rice's comments:

The work group decided to not accept changes related to plan/focus of work group, as the existing language was used as the basis for all work group discussions.

The work group added the words "or positive" for the recommendation on page 3 (comment CR3). The sentence now reads as follows: "Were there any adverse or positive actions taken by the employer...."

In the sentence following the above mentioned edit, the work group decided to leave the word "you" instead of substituting "everyone."

The work group added the words "and successes" on page (comment CR5), to read "NIOSH policies should be developed to address identified problems and successes."

The work group changed "protecting workers" to "reducing exposures" on page 7 (comment CR8), to read "Effective interventions that are discovered or validated in NIOSH research are only useful in reducing exposures to the extent that they are fully communicated and implemented."

Jim Platner's comments:

Changed NLR A(a)(5) to NLRA(a)(2)

In response to Jim Platner's 8/30/2013 email: Added the following sentence on page 4 (2nd issue): "It is essential to understand the workforce and work environment in order to develop procedures that will encourage participation."

John Decker will send a revised draft incorporating changes to the full BSC.

A copy of draft will be included in the briefing book for the BSC members.

BSC presentation on September 18

Bill Kojola will be the primary presenter for the work group. The agenda has one hour allotted to the topic. Bob Harrison will bring a laptop to the BSC meeting and will make any necessary changes to the draft report in response to BSC discussion.

Appendix B: Work Group Report

Report and Recommendations

Board of Scientific Counselors Work Group

National Institute for Occupational Safety and Health

Structuring Labor-Management Participation in Research Partnerships:

Request for Analysis and Recommendations

September 2013

The National Institute for Occupational Safety and Health (NIOSH) conducts research in various work settings with differing labor-management structures. In some of those settings, workers are represented by a labor organization. Increasingly however, NIOSH conducts its research in nonunion workplaces. The differences in these labor-management relationships between organized and unorganized workplaces may impact the conduct of research and possibly introduce bias that can affect results. NIOSH is interested in measures to ensure the best possible research outcomes within the context of these labor-management structures.

In partnership with Toyota Motors Engineering & Manufacturing North America, Inc., NIOSH has initiated a research study to evaluate interventions to reduce the risk of shoulder injuries in overhead automotive assembly work. Workers at the Toyota facility are not represented by a labor organization. This research study, along with other research studies deemed appropriate, present an opportunity for case-study analysis by the Board of Scientific Counselors (BSC). The NIOSH Director has asked for the BSC to provide review and recommendations.

BSC Charge:

The BSC is charged with providing analysis and recommendations to the NIOSH Director on how best to conduct participatory research in contemporary work settings where workers have a legal representative and those where workers do not. The NIOSH Director is especially interested in

recommendations about how best to structure labor-management participation to obtain quality data. In addition, the NIOSH Director would welcome any recommendations that would further enhance the scientific quality of the planned intervention study while ensuring that worker participation in the study is entirely voluntary and that the results of the study pertaining to individual workers remain confidential. The BSC may form a work group to conduct the analysis. After developing initial recommendations, the BSC will present their recommendations to the Director in a public meeting.

In response to the charge given to the BSC, a work group of volunteer BSC members was formed to conduct the analysis. The work group conferred by teleconference on six separate occasions. The report and recommendations below are provided to the BSC for its consideration and adoption.

Following the initial teleconference meeting that included a review of the charge, a presentation from NIOSH researchers on the Toyota musculoskeletal intervention study, and a review of the NIOSH “Tripartite Review” policy document (designed to keep interested and affected government, labor, and management groups informed and engaged in field studies, including pre-study and post-study procedures and information on progress of a study), the work group adopted the following plan going forward:

Use the Toyota study as an opportunity to build in process evaluation with focus on workers. We will not critique or focus on study design per se, but use this as an opportunity to improve our understanding of how we can best engage workers in NIOSH studies. The information learned from this study can help NIOSH improve their guidelines for joint labor/management participation protocols and procedures for researchers. Possible issues to focus on:

What are the practical, effective and feasible methods to ensure worker involvement and get the study information out to those who can use it?

What worked most effectively in the study to enhance and ensure worker participation?

What was understood by the workers about study design?

Was there any coercion involved?

What are the mechanisms for protecting workers against potential adverse social/economic consequences?

What benefits did workers see in being involved?

Why did they participate in the study?

Did they understand the results (and what did they understand)?

What action would workers take based on the study?

Did anything actually change on the shop floor as a result of the study?

What methods were implemented to monitor the findings and possibly end the study before the end?

During its deliberations, the work group discussed the issues identified in this plan outlined above, as well as other issues that arose in the discussions, received updates on the progress of the Toyota study from NIOSH researchers, and reviewed various relevant NIOSH documents and policy statements. In addition, we heard presentations from BSC member James Platner on issues related to employee involvement in occupational safety and health research and from members of the NIOSH Institutional Review Board (IRB) on the agency's IRB process and makeup.

Recommendations

Issue #1: Voluntary, non-coercive and confidential participation of workers in NIOSH field/intervention studies is essential in order to obtain quality data regardless of differing labor-management structures where the research is being conducted. In a unionized workplace, employees have legal representation and grievance/arbitration procedures that can protect workers from any adverse consequences an employer may impose when workers do not volunteer to participate, are coerced to participate or not participate, or where participant confidentiality is breached by the employer. In a non-union workplace, these protections do not exist for employees. In addition, communication of research findings to workers in non-union settings is more challenging, as workers do not have organizations through which NIOSH can communicate its findings. Where workers are represented, their union offers an avenue for communicating findings. The Toyota study, which is now underway in the field, is being conducted where workers are not represented by a union. The presence of any barriers to employee participation in this study and the extent and impact of the communication of research findings need to be explored.

Recommendation:

NIOSH researchers involved in the Toyota study should conduct a "follow-back" survey of workers at the completion of the project to obtain feedback on the issues of barriers to participation and communication of findings. For example, questions to consider include: Did workers believe their participation was voluntary? Were there barriers to participating and if so, what were those barriers? Did employees believe the information they provided to NIOSH to be held in confidence? Were there any adverse or positive actions taken by the employer for workers who participated – or for those who did not? Did NIOSH or the employer inform you of the results of the study? Did workers believe the study was valuable? Did any changes occur in the workplace as a result of the study? Were the changes beneficial? NIOSH researchers can use the recent follow back surveys of the Health Hazard Evaluation (HHE) program to assist them in crafting questions. A summary of the survey findings should be compiled, analyzed, and lessons learned developed and written that can be applied to future field/intervention projects, in both union and non-union workplaces, to help ensure voluntary participation, identify barriers to participation, confidentiality, and communication of research findings in future studies.

Issue #2: Beyond the Toyota study, NIOSH will continue to grapple with how best to conduct collaborative research in current work settings where workers have union representation and where workers do not. It is essential to understand the workforce and work environment in order to develop procedures that will encourage participation. The issue of ensuring voluntary, non-coercive and

confidential participation of workers in NIOSH field/intervention studies in order to obtain quality data will continue to be a challenge as will the issue of NIOSH addressing any differences in achieving this objective between union and non-union workplaces. In some situations, NIOSH will conduct a study off-site in circumstances where employers are not cooperative or will meet with workers alone offsite. NIOSH also notifies workers that they may contact NIOSH staff for private conversations. Nevertheless, NIOSH needs to gather additional information in its field studies on situations and circumstances that create barriers to participation or where adverse consequences have occurred so that policies and approaches can be developed to prevent these occurrences from happening in future studies.

Recommendation:

When necessary, NIOSH should continue to conduct study activities off-site in circumstances where employers are not cooperative and offer to meet with workers off-site to maintain confidentiality. In addition, NIOSH should conduct “follow-back” surveys in selected union and non-union field/intervention studies to collect information on the views of workers, and union representatives in workplaces where employees are represented. The surveys should focus on issues of voluntary of participation, barriers to participation, and whether any adverse consequences occurred to workers who participated or failed to participate. The findings of these surveys should be summarized and analyzed, with a focus on identifying barriers to voluntary participation and circumstances that may result in adverse consequences experienced by workers. NIOSH policies should be developed to address identified problems and successes

Issue #3: Workers who participate in studies often have helpful input on such things as how the study can be successfully integrated into their workplace, what types of incentives would be meaningful, and on how questions can be asked to be relevant to the work environment. Often, study protocols are finalized before the workplace is integrated into the study process.

Recommendation:

In circumstances where NIOSH researchers believe it is appropriate, they should use worker-guided or worker-participatory research methods, which would entail some pre-study integration of representative workers and/or employers prior to finalization of study protocols. These approaches can help identify issues prior to study implementation so that they can be addressed in the design phase.

Issue #4: Institutional Review Boards (IRB), including the NIOSH IRB, typically address issues related to physical harm that may be connected to the proposed research project being reviewed. The NIOSH IRB also considers other types of harms, including whether there are any potential economic/social consequences that may be connected to its workplace studies, for example, whether medical information could impact health insurance of a worker. Under federal regulations regarding IRB membership, 45 CFR 46.107(c) states that “Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.” The NIOSH IRB includes representatives from various disciplines and has the ability to call on outside expertise when needed. An IRB review of a research proposal is an important step early in the research process for identifying and correcting potential problems that may result in social or economic

harm to workers. NIOSH needs to ensure that its IRB is sufficiently focused on assessing social/economic harm during its review of research proposals as an early means to protect workers against experiencing adverse consequences.

Recommendation:

The NIOSH IRB is encouraged to continue, and strengthen, its evaluation of the potential economic and social consequences that may be connected to research proposals it reviews. Particular focus should include an examination of any barriers to participation in research and ensuring that confidentiality is upheld. The IRB is also encouraged to secure the expertise it needs to accomplish this objective.

Issue #5: The National Labor Relations Act (NLRA) governs labor-management relationships and structures between employers, employees, and unions in workplaces where employees are represented. Section 8(a)(2) of the NLRA makes it illegal for an employer to "dominate or interfere with the formation or administration of any labor organization or to contribute financial or other support to it". A labor organization is broadly defined to include an employee representation committee in which employees participate for the purpose of dealing with employers over a range of issues, including conditions of work (such as safety and health). A violation of this Section can be committed where an employer dominates a safety and health committee in a unionized workplace or when an employer creates and dominates a safety and health committee in a non-union situation. NIOSH researchers may be involved or interacting with safety and health committees seeking employee participation in the course of their research or studies. NIOSH must be careful not to encourage employers to form, dominate, or interfere with a safety and health committee in any manner that violates Section 8(a)(2).

Recommendation:

Where employee participation is sought in field/intervention studies, NIOSH researchers involved should be made aware of and receive education on the provisions of the National Labor Relations Act (NLRA) that govern labor-management relationships, including Section 8(a)(2) of the NLRA that prohibits an employer from dominating or interfering with the formation or administration of a labor organization.

Issue #6: NIOSH does not conduct studies involving treatment such as those of NIH that assess the efficacy of experimental drugs in clinical trials. Thus, NIOSH studies do not generally involve benefits/risks in the same manner that clinical trial treatment research entails, nor does NIOSH generally receive reports of adverse health events directly from study subjects. However, NIOSH does have a formal program for study project officers to contact the IRB office whenever an adverse event (anything outside the protocol) occurs and a formal process for categorizing and analyzing these adverse events or unanticipated risks to subjects. NIOSH does not have a formal process for systematically identifying adverse events to subjects while the study is in progress. NIOSH intervention studies, particularly randomized control study designs, could potentially result in subjects (workers) experiencing, during the course of a study, an intervention that is clearly superior to that of other interventions being evaluated or an intervention that clearly represents risks to the workers. In clinical trials, NIH sometimes establishes Data and Safety Monitoring Boards to ensure the safety of participants by monitoring the

results at specified interim time periods and, take action to continue the study unmodified, modify the protocol, or terminate the trial on the basis of the accumulating data on risk/benefit.

Recommendation:

For intervention studies, including randomized control trial study designs, NIOSH researchers should consider mechanisms to monitor the progress of the study, including outside monitoring experts or a safety committee. Such a mechanism can help ensure the health and safety of participants and provide unbiased input when interim study data is examined, when assessing benefits and risks to participants, and to provide input on necessary actions to modify, terminate, or continue the study.

Issue #7: Informing employees and employers of the findings of NIOSH intervention studies, like the Toyota project, is a critical element of ensuring that the findings are used to address hazards and make workplaces safer. Effective interventions that are discovered and validated in NIOSH research are only useful in reducing exposures to the extent that they are fully communicated and implemented. In February 2013, NIOSH issued new policy documents involving communication of the results of epidemiological studies and environmental sampling/monitoring results (“Risk Communication Policy for NIOSH Epidemiologic Studies” and “Notifying Workers of Individual Environmental Sampling and Monitoring Results”). However, no equivalent NIOSH policy document exists that focuses on communicating the findings of NIOSH intervention studies.

Recommendation:

NIOSH should develop a new policy or guideline document that addresses the communication of results of all studies where the research was conducted. The policy should include dissemination approaches for providing the information to employers, workers, and unions where employees are represented. NIOSH should also develop a communication/information strategy for more broadly disseminating the findings to relevant similar and affected industries and occupations.

Issue #8: When NIOSH conducts field/intervention studies, typically an informal “letter of agreement” is prepared, prior to initiating the research, between the employer and NIOSH and submitted to the IRB. These letters are general in nature and are used to demonstrate the good intention of the employer to participate in the study. Other than showing a good intention to participate in the study, employers usually agree to nothing else. No specific details about the study are included in this letter and NIOSH has no criteria established for determining the minimum content of a letter of agreement.

Recommendation:

NIOSH should consider developing some general criteria or guidelines for minimum elements that must be contained in a letter of agreement beyond that of an employer demonstrating its good intention to participate in the study. The letter might contain some additional elements, such as stating that employee participation will be voluntary, employees can withdraw from participation at any time during the study without reprisal, and that confidentiality will be maintained. Other issues specific to the particular study being conducted could also be included in the letter.

Issue #9: Addressing issues that impact research outcomes in differing labor-management structures to assure the best possible outcomes is an important undertaking. The Board of Scientific Counselors recommendations initiate a process that will hopefully begin to identify issues and potential problems and solutions that can impact the quality of results as well as determine the circumstances that provide assurances that employee participation will truly be voluntary, that confidentiality will be maintained, and that employees will not suffer reprisals for their participation or lack thereof. We see this effort as an ongoing process that NIOSH needs to evaluate on a periodic basis.

Recommendation:

In one year from the adoption of these recommendations, we recommend that NIOSH report back to the Board of Scientific Counselors on the progress and findings of the recommendations and its response to addressing issues and problems that have been identified. NIOSH should also continue the process of identifying issues related to labor-management structures that impact outcomes and employee participation in the future and report back periodically to the Board.

Work Group Members

Robert Harrison, Co-Chair

William Kojola, Co-Chair

Bonnie Rogers, BSC Chair

Corinne Peek-Asa, BSC Member

Michael Larranaga, BSC Member

Jackie Nowell, BSC Member

Designated Federal Official

John A. Decker

The BSC members voted and approved this report unanimously on September 18, 2013.

Appendix C – Letter to Dr. Howard

September 24, 2013

John Howard, M.D.

Director

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention

Department of Health and Human Services

395 E Street, S.W., Suite 9200

Washington, D.C. 20201

Re: The Vital Role of NIOSH Education and Research Centers and Centers for Agricultural Disease and Injury Research, Education and Prevention

Dear Dr. Howard:

In accordance with the section of its Charter that calls on the Board of Scientific Counselors (BSC) to advise you on “relevant needs in the fields of occupational safety and health”, the Board wishes to respectfully convey its finding that NIOSH’s 18 Education and Research Centers (ERCs) and 9 regional Centers for Agricultural Disease and Injury Research, Education and Prevention (Ag Centers) represent indispensable components of NIOSH’s efforts to reduce occupational injury and illness in the United States. NIOSH’s intramural and extramural research and innovation programs are recognized worldwide for their excellence in assessing the nature and prevention of workplace health hazards. The BSC believes that the preventive value of NIOSH research and innovation will suffer substantially if the professional education activities of the ERCs and the Ag Centers are reduced or eliminated.

Through their support of graduate educational programs, the ERCs supply over 75% of the nation’s occupational safety and health professionals in specialty areas like occupational medicine and advanced injury prevention. These graduate programs, together with the ERCs postgraduate and professional development programs for practicing safety and health professionals, represent the only viable means of supplying the professional workforce that is essential to translating NIOSH’s research advances into practice. In like manner, the Ag Centers represent the only substantive federal effort that offers state of the art educational outreach targeted to health professionals, managers and workers in the agricultural sector.

The capacity of NIOSH to fulfill its mission depends significantly on continuation of the vigorous educational activities provided by the ERCs and Ag Centers. These educational activities are unlikely to be replicated or replaced by alternative programs. Moreover, the faculty and trainees supported by ERCs and Ag Centers contribute significantly to research and innovation in occupational safety and health. Steps by NIOSH to maintain the ERCs and Ag Centers, and to inform the nation of their crucial importance, address a highly relevant need in occupational safety and health.

Sincerely,

NIOSH Board of Scientific Counselors

A handwritten signature in black ink that reads "Bonnie Rogers". The signature is written in a cursive, flowing style.

Bonnie Rogers, M.E., B.S.N., M.P.H., Dr.PH.,

Chair, NIOSH Board of Scientific Counselors

Professor and Director of Occupational Safety and Health

University of North Carolina School of Public Health

David K. Bonauto, M.D., M.P.H.

Associate Medical Director

Safety and Health Assessment & Research Prevention Program

Washington State Department of Labor and Industries

Kitty H. Gelberg, Ph.D., M.P.H.

Director, Bureau of Occupational Health and Injury Prevention

New York State Department of Health

Robert Harrison, M.D., M.P.H.

Professor of Medicine

Division of Occupational and Environmental Health

University of California, San Francisco

Darryl C. Hill, Ph.D., C.S.P.

Executive Director, Health & Safety

Global Employee Relations

Johnson Controls Inc.

Clarion Johnson, M.D.

[former] Medical Director

Exxon Mobil Corporation

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Division of Clinical Pharmacology and Toxicology

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Professor and Department Head

School of Fire Protection and Safety

Oklahoma State University

John Mendeloff, Ph.D.

Professor, Graduate School of Public and International Affairs

University of Pittsburgh

Jacqueline Nowell, M.P.H.

Director of Health and Safety

United Food and Commercial Workers

Corinne Peek-Asa, M.P.H., Ph.D.

Professor

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CPWR – The Center for Construction Research and Training

James D. Ramsay, Ph.D., M.A., C.S.P.

Professor of Homeland Security

Embry-Riddle Aeronautical University

Carol Rice, Ph.D., C.I.H.

Professor Emerita

Department of Environmental Health

University of Cincinnati

Certification Statement

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the September 18, 2013, meeting of the NIOSH Board of Scientific Counselors, CDC are accurate and complete.

October 31, 2013

A handwritten signature in black ink that reads "Bonnie Rogers". The signature is written in a cursive style with a large initial "B" and a long, sweeping underline.

Date

M.E. Bonnie Rogers, MPH, DrPH, COHN-S

Chair, NIOSH Board of Scientific Counselors