DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date May 18, 2016

From Angela M. Morley
Chair, NIOSH Institutional Review Board

Subject IRB Exemption Determination for NIOSH Protocol 16-DART-01XM, "Survey of MSD Prevention Tools/Methods: 10-year Follow-Up"

To Brian D. Lowe
Project Officer, [NIOSH/DART]

On behalf of the NIOSH Human Research Protection Program (HRPP), I reviewed the request to exempt 16-DART-01XM, and find this research activity (administration of the survey) is exempt under 45 CFR 46.101(b)(2). This determination is valid for a period of three years through May 17, 2019**.** However, we strongly encourage investigators to close out exempt protocols as soon as NIOSH staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

Please be aware changes to this protocol may not be implemented until they are reviewed by the NIOSH HRPP and determined to be consistent with the exemption categories. You will be reminded in three years (if the study has not been completed and closed) to submit another request for continuation and to confirm that no changes have been made to the protocol or the related science that would affect the ethical appropriateness of the research or this exemption determination.

Please also be advised investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact the HRPP at cin-hsrb@cdc.gov, or by telephone at (513) 533-8591.

0.1379 Centers for Disease Control and Prevention Date Received:
NIOSH IRB (HSRB) 05/17/2016 e K Ashley

Signature Page for Human Research Review e G DeBord

Protocols and Related Documentation

Anniversary Date: _____

Use this signature page when submitting HRPO forms to your center-level Human Subjects Contact. When submitting materials with these forms, please consecutively number all pages, beginning with the protocol title page and followed by consent form(s) and ancillary documents. See *HRPO Guide: Overview* for further details. **NOTE: IRB (Institutional Review Board) refers to the NIOSH IRB-HSRB (National Institute for Occupational Safety and Health (NIOSH), Human Subjects Review Board (HSRB) of the CDC Human Research Protection Office (HRPO).**

1 Protocol Identifiers

CAN#: 939052R__ (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: HSRB 16-DART-01XM Protocol Version Number: ____ Version Date: _____

Protocol Title:

Survey of MSD Prevention Tools/Methods: 10-year Follow-Up

Amendment Number (if applicable): _____

2 Key CDC Personnel

	Name and Degrees (First Name Last Name, Degrees)	User ID	CDC SEV #	CDC NC/Division
Primary Contact Phone Number (required)	Brian D. Lowe 513-533-8161	bfl4	10556	NIOSH/DART
Principal Investigator Phone Number (required)	Brian D. Lowe 513-533-8161	bfl4	10556	NIOSH/DART

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/Division is the national center or equivalent and division or equivalent, or coordinating center or office if submitted at that level.

3 Forms Submitted with this Signature Page

Check all that apply in the appropriate column.

IRB-Reviewed Protocols	Exempted Protocols (All shaded will not apply here)
☐ 0.1250: Initial Review by IRB	☒ 0.1250X: Initial Review for Exemption
☐ 0.1251: Continuing Review of Approved Protocol	☐ 0.1251X: Continuing Review of Exempted Protocol
☐ 0.1252: Review of Changes to Approved Protocol	☐ 0.1252X: Review of Changes to Exempted Protocol
☐ 0.1254: Incident Report	
☐ 0.1254S: Supplemental Adverse Event Report	
☐ 0.1253: End of Human Research Review	☐ 0.1253: End of Human Research Review
☐ 0.1370: CDC's Research Partners	☐ 0.1370: CDC's Research Partners
☐ 0.1371: CDC Rely on a Non-CDC IRB	
☐ 0.1372: Outside Institution Rely on a CDC IRB	
☐ 0.1373: CDC Cover an Individual Investigator	

4 Signatures

As principal investigator, I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date Signed	Remarks
Principal CDC Investigator: Brian D. Lowe -S (Digitally signed by Brian D. Lowe -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Brian D. Lowe -S, 0.9.2342.19200300.100.1.1=1000081744 Date: 2016.05.16 15:31:24 -04'00')	05/16/2016	

As a supervisor of the principal investigator, I hereby accept responsibility for ensuring that this CDC-sponsored research project is conducted in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date Signed	Remarks
Team Lead: Stephen Hudock -S (Digitally signed by Stephen Hudock -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Stephen Hudock -S, 0.9.2342.19200300.100.1.1=1001277359 Date: 2016.05.17 08:13:30 -04'00')	05/17/2016	☐ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): Edward M. Hitchcock -S (Digitally signed by Edward M. Hitchcock -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000297126, cn=Edward M. Hitchcock -S Date: 2016.05.17 10:52:46 -04'00')	05/17/2016	☐ PI is Branch Official
Division Official (e.g., Director or ADS): Kevin E. Ashley -S (Digitally signed by Kevin E. Ashley -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000686406, cn=Kevin E. Ashley -S Date: 2016.05.17 10:49:35 -04'00')	05/17/2016	☐ PI is Division Official

I concur that this CDC-sponsored research project is consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants* and with other applicable CDC and national center policies.

Signature	Date Signed	Remarks
/Chair NIOSH IRB-HSRB: Angela Morley -S (Digitally signed by Angela Morley -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Angela Morley -S, 0.9.2342.19200300.100.1.1=1000726807 Date: 2016.05.18 11:19:33 -04'00')	5/18/16	
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

THIS SECTION FOR CDC/NIOSH IRB-HSRB OFFICE USE ONLY:
Expedited Review ☐; Minimal Risk ☐; as provided for in 45CFR46.110.
(b) (1) category(s) _____
Approved Review ☐ for one year; **Renewal Date:** _____
CDC 0.1250 cites Estimated Subject # is _____ Subject # to Date is _____
Approved/Amended Subject # is _____
COMMENTS: _____
Full/Convened Board Review Approved ☐ Meeting Date Approval: _____

5 Additional Comments

6 Reminder Regarding Other Regulatory Clearance Processes

The principal investigator is responsible for obtaining other regulatory reviews as needed, which may include OMB clearance under the Paperwork Reduction Act (PRA) for federally sponsored information collections. Approval by or exemption from the IRB is unrelated to OMB clearance requirements under the PRA. For more information on whether your study requires clearance under PRA or other regulations, please consult the appropriate officials within your national center.

5/17/2016 e K Ashley
e G DeBord

Request for Exemption from Human Subjects Regulations

Use this form to submit a protocol for exemption from human subjects regulations. See *HRPO Guide: Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 16-DART-01XM Protocol version number _____ version date _____

Protocol title: Survey of MSD Prevention Tools/Methods: 10-year Follow-Up

Suggested keywords (optional). Enter each term in a separate cell:

ergonomics	MSDs	_____
_____	_____	_____

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Brian Lowe, Ph.D.	bfl4	10556	NIOSH/DART
Principal investigator (required)	Brian Lowe, Ph.D.	bfl4	10556	NIOSH/DART
Investigator 2	Patrick Dempsey, Ph.D.	pbd8	9252	NIOSH/OMSHR
Investigator 3	Evan Jones, B.S.	eoj1	6568	NIOSH/DART
Investigator 4	_____	_____	_____	_____
Investigator 5	_____	_____	_____	_____

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center (or equivalent) and division (or equivalent), or coordinating center or office if submitted at that level.

List all other CDC investigators, if any. Include name and degrees, user ID, SEV #, CDC NC/division:

_____

3 CDC's role in project

Check yes or no for each of the following.

☒y ☐n CDC employees or agents will obtain data by interacting with participants.

☐y ☒n CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

☐y ☒n CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens.

☐y ☒n CDC employees will provide substantial technical assistance or oversight.

☒y ☐n CDC employees will participate as co-authors in presentation(s) or publication(s).

"Agents" includes on-site contractors, fellows, and others appointed or retained to work at a CDC facility conducting activities under the auspices of CDC.

4 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) and other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support) for this research activity, as well as collaborators who do not receive such support. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners.

☐ Research partners are listed on form 0.1370, which accompanies this form.

5 Study participants—planned demographic frequencies

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: Exempt Review Cycle* for definitions.

Number of participants	938
Location of participants	
Participating at domestic sites	938
Participating at foreign sites	0
Sex/Gender of participants	
Female	200
Male	738
Sex/gender not available	0
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	938
Race of participants	
American Indian or Alaska Native	0
Asian	0
Black or African American	0
Native Hawaiian or Other Pacific Islander	0
White	0
More than one race	0
Race not available	938

Comments on demographics

6 Regulation and policy

6.1 Exceptions or restrictions on exemptions

Check yes or no for each of the following.

☐y ☒n Research poses greater than minimal risk to participants.
CDC does not exempt research that poses greater than minimal risk to subjects.

☐y ☒n Research involves prisoners (either intentionally or incidentally).
These exemptions do not apply to research involving prisoners.

☐y ☒n Research involves interaction with children or obtaining identifiable private information about children through surveys or interviews of others.
The exemption at category 2 is restricted when children are research subjects.

6.2 Exemption categories

Check all that apply. See *HRPO Worksheet for Exemption from Human Subjects Regulations* for details.

Educational practices

- ☐ 1 Normal educational practices in commonly accepted educational settings

Educational tests, surveys, interviews, or observation of public behavior

- ☐ 2a Adults only; data are not identifiable
- ☒ 2b Adults only; data may be identifiable but are not potentially damaging
- ☐ 2c Children; limited to use of educational tests or observations of public behavior when the investigators do not participate in the activities being observed
- ☐ 3a Public officials or candidates
- ☐ 3b Federal statute requires confidentiality during and after research

Existing data, documents, records, pathological specimens, or diagnostic specimens

- ☐ 4a Publicly available sources
- ☐ 4b Information recorded by the investigator such that participants cannot be identified, directly or through linked identifiers

Research and demonstration projects (subject to the approval of the HHS Secretary)

- ☐ 5a Public benefit or service programs
- ☐ 5b Procedures for obtaining benefits or services under those programs
- ☐ 5c Possible changes in or alternatives to those programs or procedures
- ☐ 5d Possible changes in methods or levels of payment for benefits or services under those programs

Taste and food quality evaluation and consumer acceptance

- ☐ 6a Foods that are wholesome without additives
- ☐ 6b Foods that contain an ingredient, chemical, or contaminant at a level found to be safe

7 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

- ☒ Complete protocol
- ☐ Documentation in support of exemption 3b, if applicable (e.g., §308(d) Assurance of Confidentiality)
- ☒ Peer reviewers' comments or division waiver (NIOSH)
- ☒ Consent, assent, and permission documents or scripts
- ☒ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts)
- ☒ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools)
- ☐ Certification of IRB approval or exemption for research partners

8 Additional comments

This data collection consists of a web-based survey that will only be administered to professional ergonomists with a specific certification through one of the International Ergonomics Association (IEA) endorsed accreditations. This highly specific group of eligible participants possess education at the level of a 4-year university degree plus post-graduate training in almost all cases. We do not believe that reading level assessements for written materials are necessary as would be typical for surveys and consent forms for a worker population. An informed consent statement is attached.

NIOSH Study Protocol

TITLE OF PROJECT (Limited to 60 characters, including spaces. Please Do Not put the project title in ALL CAPS.)
Survey of MSD Prevention Tools/Methods: 10-year Follow-Up

PROJ. OFFICER (Last, first middle)
Lowe, Brian D.
POSITION TITLE
Research Industrial Engineer
DIVISION/LABORATORY/OFFICE AND BRANCH
Division of Applied Research and Technology/Organizational Science and Human Factors Branch
Email Address
bfl4@cdc.gov
TELEPHONE (Area code, number)
(513) 533-8161

HUMAN SUBJECTS: Will this project utilize human subjects? (Yes/No)	Yes
VERTEBRATE ANIMALS: Will this project utilize vertebrate animals? (Yes/No)	No
Species of animals to be used:	n/a
Approximate number of animals to be used:	n/a
Radionuclide Use? (Yes/No) If "Yes," please Address in the Health and Safety Plan Section	No

Table of Contents

Key Personnel

NAME	ORGANIZATION	ROLE ON PROJECT
Lowe, Brian	NIOSH/DART	Project Officer
Jones, Evan	NIOSH/DART	Computer/IT support
Statistical Support Team	NIOSH/DART	Statistical Support (ad hoc)
Dempsey, Patrick	NIOSH/OMSHR	Consultant

A. Background and Significance

The purpose of this project is to administer a large scale survey of ergonomics professionals as a 10-year follow-up to a survey conducted of U.S. Certified Professional Ergonomists (CPEs) by Dempsey et al and published in 2005 (see Appendix A). The project will extend the original survey conducted by Dempsey et al (2005) in two ways: (1) the sample will be broadened to the international community of ergonomics practitioners, and, (2) the queried tools and methods will be modernized to reflect new and emerging technologies not included in the original survey. The purpose of the original survey will be unchanged - to gather information on the types of basic tools, direct and observational measurement techniques, and software used in the field by ergonomics practitioners to assess risk factors for musculoskeletal disorders and to evaluate workplace interventions (Dempsey et al., 2005). The recent NIOSH intramural funding opportunity for small studies in the area of musculoskeletal disorders (MSD) prevention offered a timely opportunity to conduct an important follow-up survey to assess current trends in the field and compare/contrast the practice to the findings reported in 2005.

The motivation for the original 2005 survey was to better understand the types of tools and methods practitioners use, their opinions of these tools, and to potentially gain an understanding of the constraints or preferences that influence this selection. At the time of the 2005 survey there were many tools reported in the literature, but little information on the extent to which these different tools were used by practitioners. Similarly, there was little published information on users' experiences with these different tools. There has been considerable interest in the findings and the Dempsey et al (2005) publication has been widely cited. We anticipate that a follow-up effort will result in even greater interest as changes in the practice of ergonomics and prevention of soft tissue MSDs can be inferred from comparisons between the two surveys time points.

Since publication of the initial survey findings there has been a proliferation of smart phone/smart device-embedded gyroscopic and linear acceleration sensors and related "apps" for human motion and activity logging. Further, the capture of digital still photos and video is now trivial with small touchscreen mobile pads, tablet and smartphones. In the 2005 survey summary digital and video cameras were used by 87% and 96%, respectively, of the respondents. Little is known about the extent to which ergonomics practitioners are using

newer technologies towards assessing workplace physical activity (and now, workplace *inactivity* and "sedentarism") and other job demands. Thus, the survey will provide a contemporary perspective on the scope of use of assessment tools and methods by these professionals.

MSD Program Strategic Goal 16PPMSDSG2 is to: *Reduce the incidence of work-related MSDs by implementing practical and effective workplace interventions to reduce exposure to MSD risk factors.* This small study does not directly addresses the effectiveness of various ergonomics and MSD prevention methods for assessing workplace interventions, however the results will clearly be used to understand the prevalence of use of those methods by practitioners within the discipline. Results of this study will have implications for dissemination efforts related to musculoskeletal disorder risk assessment tools and methods since they will provide insight into the current practices of ergonomics professionals. It is ineffective to continue dissemination efforts for tools and methods that practitioners do not have a need for or do not find useful.

The project is innovative in that we are not aware of any *international* formalized web-based survey of tools and methods used by ergonomics practitioners in the assessment of workplace risk factors having ever been conducted. The study by Dempsey et al. (2005) is the most comprehensive data we are aware of on the degree of use of various tools and techniques for MSD risk factor assessment. With time, the development and acceptance of newer technologies, and new emerging issues of relevance to the scope of ergonomics practice the 2005 study becomes increasingly dated.

B. Specific Aims

The proposed project has the following aims:

Aim 1: *Extend the original ergonomist survey population to include the international community of practicing ergonomists.* This will serve to better characterize the current scope of practices of the international community of specialists working in the field of MSD prevention and to formally determine international use of various tools and techniques. Specific attention will be given to quantifying international use of the NIOSH Lifting Equation (NLE) - to determine whether its high use (83%) reported among U.S. ergonomics practitioners in 2005 is similar internationally, and if this use has increased domestically since the 2005 survey.

Aim 2: *Through modification to the original survey items and queries, determine the use of contemporary technologies that in the 2005 survey were not yet available, or used by only the earliest adopters.* One specific example is the use of touch screen smartphone or pad/tablet devices with photo and video capture capabilities, and associated use of mobile applications ("apps" on Android, Apple iOS, etc., platforms.) A second example includes the class of physical activity monitoring technologies based on popular consumer-grade smartphone/smartwatch/app activity monitoring systems (e.g. "FitBit" and "Pebble" devices). This aim aligns with Total Worker Health™ objectives related to physical activity promotion as a part of workplace safety and health. Surveying the use of these technologies will assess

the degree to which the ergonomics scope of practice may be evolving to include the assessment of physical activity exposure at both extremes - occupational overuse vs. occupational sedentarism. This topic has generated significant interest, evidenced by increases in conference, journal and professional ergonomics publications (i.e. "Combating the Sedentary Workplace: Is Sitting Too Much Bad for Your Health", *Ergonomics in Design*, July 2015, vol 23, issue 3). The current use of these new technologies, as well as their desired use among practitioners without access to them, will be determined to inform researchers about dissemination choices that best match the current scope of practice.

C. Study Design and Methods

Phase I: Survey Update and Revision

This phase will consist of identifying tools and methods that should be added to the existing questionnaire. Existing tools/items from the original survey will be kept unchanged in their original format for facilitating direct comparison between responses at the two points in time. Because of the international expansion of the survey we will add the response option of "regulatory requirement(s)" as a reason for use of analysis methods. While this response is not relevant to U.S. practitioners it may be so for international respondents.

New survey items to be added to the tools/methods list will be identified and pilot tested in a manner similar to that described by Dempsey et al. (2005). The *categorization* of tools and methods may require some restructuring in light of newer technologies. For instance, in the 2005 survey the *video camera, laptop, and personal digital assistants* were individually classified in the category of "Basic Measurement Tools" (section 6). As of 2015, pad or tablet devices with an integrated camera (still and video image capture) serve as a hybridized version of these tools. This will involve restructuring of the form. Another technologic example in need of consideration is that of consumer gaming consoles that are now capable of lower resolution markerless motion capture. This technology is moving closer to viability in field environments for low cost assessment of worker motion in industry. Such technologies may be worthy of consideration in section 8 – Direct Measurement Techniques. A second newer technology to consider for inclusion in section 8 are physical activity monitoring devices in the form of wearable smart devices.

We will further modify the survey to contain questions that cover use of *apps* from smart device platforms by Google and Apple. Due to the large potential number of apps (especially those centered on office ergonomics), the survey will ask about use of apps by categories (e.g. office ergonomics, materials handling, etc.). Further, we will consult with the internal NIOSH TWH program, and possibly its extramurally funded Centers, to identify existing TWH toolkits and/or evaluation approaches (for example, the CDC Worksite Health ScoreCard).

Commented [LBD(1]: It was decided that use of "apps" and TWH methods will be queried as free response questions on the survey.

Because of the expansion of the survey to query ergonomics practitioners internationally, a modification to response categories will be made to reflect regulatory directives that exist outside of the U.S. A response option will be added to indicate that a reason for using a measurement technique, tool, or method might be based on regulatory compliance.

Another planned addition to the survey will be a question about effective modes of dissemination of information. The purpose of this item will be to identify the types of information products or sources (e.g. scientific literature, trade journal literature, society newsletters, technical reports, professional conferences, mobile applications, etc.) that are most utilized by ergonomics practitioners to keep informed about current and emerging issues, assessment techniques and methods.

The pilot testing will have three steps:

1. We will conduct an informal review of practitioner-oriented conference programs of ergonomics societies (e.g. National Ergonomics Conference & ErgoExpo, Applied Ergonomics Conference, etc), society newsletters, and possibly keyword search frequencies in ergonomics databases. This will be for the purpose of identifying emerging issues that have related methods and/or tools of relevance.
2. After integrating question items on what we identify as emerging issues, tools, and methods not represented in the 2005 survey we will seek input on the updated set of tools/methods and the resulting revision of the original survey questionnaire by the NIOSH MSD Cross Sector Program.
3. A small group (less than 10) of certified ergonomics practitioners will be engaged to participate in a survey pilot and provide feedback on the integration of new items into the questionnaire and the web interface used to administer (a new aspect of the survey). We intend to seek input from ergonomists in the U.S., Netherlands, UK, Sweden, Switzerland, and Canada through participation in a pilot version of the survey. Feedback will be obtained through individual level telephone-based debriefings/consultations. Inclusion of the international pilot group will also address potential issues of country/cultural bias in the methods and tools included in the survey. We will consider including faculty of university symposiums and short courses that provide instruction on using selected tools (e.g. Harvard School of Public Health, UCLA Ergonomics Symposium, U-Michigan, Center for Ergonomics, Ohio State University courses, and others).

Commented [LBD(2]: These steps have been completed. We received input from over 15 professional ergonomists in the U.S., Canada, and UK. We met with 10 U.S. ergonomists face to face at the 2016 Applied Ergonomics Conference.

(Note: The revised questionnaire is shown in Appendix D.)

Federal information collection requests that involve survey administration with more than 10 respondents require review and clearance by the Office of Management and Budget (OMB). The timeline for this process is lengthy, and it can be expected to take up to one year to obtain OMB clearance for this information collection request. After modification and pilot testing of the questionnaire in October-February of FY16 the OMB clearance process will commence. We have planned for the possibility of a full 18 months from project start date (FY16 Q1) until the survey administration can commence in approximately March (Q2) of FY17.

Commented [LBD(3]: OMB review package will be submitted in April, 2016.

Phase II: Survey Method

A similar approach to the 2005 survey will be followed (Dempsey et al, 2005) with the exception that the survey will be administered on a web based platform. **The project team has determined that the use of SurveyMonkey® is authorized for CDC research use with limitations that would not affect this information collection request.**

Commented [LBD(4]: Survey Monkey will be used as the web platform.

Sampling Strategy. In addition to the U.S. Board of Certification of Professional Ergonomists (www.bcpe.org), from whom the investigators have obtained commitment from the Executive Director (C. Stuart-Buttle), participation will be sought internationally from other certifying organizations (see Table 1). These are primarily organizations that have been endorsed by the International Ergonomics Association (IEA). We also plan to include the Canadian College for the Certification of Professional Ergonomists whose certification requirements are consistent with those of the U.S. BCPE. We have identified approximately 1,150 potential respondents.

Table 1. Certification organizations whose members will be included as eligible participants.

Certification Organization	**Country**	**Access to Directory**	**# of Certificants**
Board of Certification in Professional Ergonomics (BCPE) AEP/*CPE designation certificants*	U.S.	yes[1]	853*
U.S. Total			**853**

European CREE in United Kingdom - Centre for Registration of European Ergonomists	European Countries	no[2]	~~456~~43
Australian Register of Certified Professional Ergonomists	Australia	yes[1]	20
New Zealand BCNZE - Board for Certification of New Zealand Ergonomists	New Zealand	yes[1]	15
Canadian College for the Certification of Professional Ergonomists	Canada	yes[1]	241
International Total			**319**

Commented [LBD(5]: Only 43 of these are in the United Kingdom

[1]Project team has full access to certificant holder contact information through public website or through BCPE membership

[2]Public access to certificant holder names, but not contact information. We will request contact information from the organization.

We will only administer the survey in English as we do not have sufficient resources for translation. We do not anticipate English language to be problematic for European, Australian, New Zealand, or Canadian participants. ~~Additionally, the team may explore the possibility of involving relevant societies within developing nations. If this is feasible, these would represent a secondary study population. Because certification processes in these~~

~~countries are likely to be unaccredited, or non-existent, responses from participants in this secondary population would be analyzed as a separate cohort.~~

All eligible respondents will be sent an initial e-mail contact with a description of the survey and its purpose (see Appendix B). This initial e-mail will be signed by the lead project investigator for the purpose of giving eligible respondents advanced notice of forthcoming e-mail correspondence that will contain a web link for survey completion. The e-mail contact distribution list of eligible respondents will be obtained from listed directories of certificants on the organizations' websites (see Table 1). As a courtesy, we will give prior notification to all of these organizations of our intent to solicit participation from their members. BCPE has already endorsed this effort.

Since the survey emphasis is on musculoskeletal disorders prevention, certificants within BCPE with a Certified Human Factors Professional designation (or equivalent) will not be contacted as eligible respondents. Individuals with this designation, at least in the U.S., do not typically engage in *physical* occupational ergonomics assessment nor musculoskeletal disorders prevention. We will invite all certificant holder members of the organizations in Table 1 to participate as eligible respondents. We will have the ability to accurately report survey response rate as the number of completed surveys divided by a denominator term comprised of the number of certificant-holders on the e-mail distribution list less any e-mail addresses that are invalid. (E-mails that are returned due to invalid addresses will not be counted in the denominator for purposes of participation rate.) Any individual from whom a survey is not received (assuming a valid e-mail delivery) will be treated as a decline of the invitation to participate. Recipients also have the option to actively decline participation in the informed consent statement. (See Appendix C for informed consent statement.) Dempsey et al (2005) did not discuss participation bias and we have no reason to suspect that non-participants would have any systematic differences in their use of tools and methods in practice than those reported by participators who do complete the survey.

~~*Contacting Eligible Participants.* We will engage an outside contractor (TKC Global, SBA-Certified 8(a) Alaska Native Corporation) to coordinate electronic mailings to the membership of the ergonomics certification organizations. Dedicated funds have been allocated for such a contract award. After the initial e-mailing the external contractor will distribute individual e-mails each with a unique web link URL address (to the same survey). The URL will be uniquely linked to a respondent's identity so that the investigators can incentivize survey participation. However, only survey responses and non-identifying personal information will be submitted through the web. The survey contains no sensitive data and no personally identifying information (PII) will be transmitted over the web through SurveyMonkey. The linkage of names to survey item responses will be through the key to the anonymous unique URL web addresses. This information will be delivered by courier to the NIOSH Washington, DC Office by the contractor in northern Virginia. The Project Officer in Cincinnati will obtain these master linkages from the NIOSH Washington Office over the CDC secured network.~~

Incentives to Participation. Various approaches to lightly incentivizing participation were explored for their consistency with NIOSH HSRB policies and past success in recruitment. At present, we are likely to forego any type of direct monetary incentive or time reimbursement for the 20-30 minute web-based questionnaire. A limiting factor is that the project funding level will preclude anything but a trivial monetary incentive for what could exceed 700 questionnaire respondents (two-thirds participation rate) that we believe reasonable to anticipate. Past

Commented [LBD(6]: We will NOT do this within the present IRB clearance request.

Commented [LBD(7]: Further information we have obtained subsequent to this protocol development indicates that this is not a feasible approach due to data confidentiality concerns. We will NOT use an outside contractor.

Commented [LBD(8]: We will NOT use a monetary reimbursement or any type of incentive.

experience (Dempsey et al, 2005) indicates that many participants will contribute this time out of professional interest and good will.

Follow-up. Follow-up reminders (two) will be sent to survey non-responders approximately four and eight weeks after the first notification is mailed. Six months will be allocated for survey administration (Q3-Q4 FY17) from the time initial e-mailing is sent to the final tabulation of data prior to statistical analysis.

Phase III: Data Analysis and Publication

Dempsey et al (2005) reported a response rate of 53% in the original survey, and we hope to achieve a significantly higher response rate with an easier web-based questionnaire requiring no physical mailing of paper surveys. Thus, we hope to exceed 700 respondents.

Analysis of the original survey consisted of descriptive statistics, primarily percentages responding affirmatively for use of each method or tool and frequency of use for each method or tool. This analysis will be repeated for the present survey administration. For those tools and methods repeated from the original survey Chi-squared tests on the proportions (proportion reporting affirmative use) will be conducted to determine if changes in the proportions are statistically different between the 2005 and present follow-up survey. For the various methods and tools we will also explore a conversion of the reported frequency of use categories (*once per year, once every 6 months, once every 3 months, once a month, more than once a week*) to ordinally scaled categories suitable for a more powerful non-parametric test, such as Wilcoxon-Mann-Whitney (Siegel and Castellan, 1988). This analysis would test for *changes in frequency of use* of the particular tool or method among the U.S. CPEs from pre-2005 to present. This would be more informative than simple changes in affirmative use. *A priori* sample size calculations are unnecessary as we will be inviting the population of eligible respondents to participate. The only factor limiting us from reporting population statistics will be the non-participation proportion. Statistical support for the project is available through the Division of Applied Research and Technology Statistical Support Team.

An additional 6-12 months after the survey administration phase is completed will be dedicated to data analysis and preparation of publications and information products. These publications would be prepared in FY18. Thus, the three-year project timeline was proposed. We anticipate a publication in a peer reviewed journal (e.g. *Applied Ergonomics*) and a NIOSH published information product, in a format to be determined, that describes the state of the art in Ergonomics and MSD prevention. We will explore other modes of dissemination of the findings through the certification organizations from which we recruit participants (listed in Table 1).

D. Study Environment

Facilities:

CDC/NIOSH/DART, Robert A. Taft Laboratory Building, 1090 Tusculum Ave, Cincinnati, OH 45226 (Rooms 344, 435, etc.): At this site, NIOSH/DART staff (Lowe, Jones) will monitor the overall project, perform data analysis, and generate publications.

CDC/NIOSH/OMSHR, Pittsburgh, PA: Dr. Dempsey, at the NIOSH Pittsburgh facility will collaborate with the Cincinnati-based investigators in all aspects of the project.

Major equipment:
The major equipment available for this project include:

DELL Desktop and Laptop Computers	CDC/NIOSH/DART Rooms 417, 435
Software : • Stata v. 11 • SAS v 9.2 • Web based survey administration platform (Survey Monkey)	 CDC/NIOSH/DART Room 349 Taft Building CDC/NIOSH/DART Room 435 CDC/NIOSH/DART Room 435

E. Protection of Human Subjects

This project will involve the collection of non-sensitive data via web-based survey questionnaire methods. Survey data relate only to respondents' professional practice within the OS&H discipline of ergonomics. Nonetheless, safeguards will be taken to insure data confidentiality and the dissociation of personally identifying information (PII) from individual questionnaire responses. The survey administration platform allows the investigator to use an e-mail invitation to send a unique URL survey link to each eligible respondent that ties survey response to the respondent's email address. This feature will be used for the purpose of tracking which individuals responded and for validating that completed surveys originate from eligible participants.

Participants' web responses will not contain PII in association with their submitted data, but the investigators will have a linkage between respondent's personal identity (name) and the individual unique URL entry to the survey. Thus, participants' identity will not be sent over the web through the survey administration system but the investigators will know the identity of individual respondents. Informed consent for participation in this study is straightforward. We anticipate approval to use electronic informed consent in which participants will acknowledge consent by "I agree" or "I decline" buttons on the website. (See Appendix C.) Basic demographic information collected over the web, including years' experience in the field, current occupation, expertise specialization, highest academic degree attained would not compromise anonymity of the

individual identity. We do not believe that any of the demographic information would be considered sensitive. No experts we discussed this with suggested that the questionnaire content contained any sensitive information.

F. Inclusion of Women, Minorities, and Children

The study population of professional ergonomics practitioners does not include children. Inclusion of women and minorities is automatic because the entire population of ***eligible*** respondents will be invited to participate. We anticipate participation among women and minorities in proportion to their demographic make-up in the membership of the societies from which we will solicit participation. Among U.S. ergonomists (BCPE organization) we anticipate a sample that is representative of female and minority participation in the ergonomics field. The representativeness of the study respondents will be compared to the known demographic composition of that organization's membership to the extent feasible.

G. Vertebrate Animals

Not applicable.

H. Staff Health and Safety Plan

There will be no laboratory or field data collection involving interaction with research participants in this project. Project staff will work in their NIOSH offices. Standard NIOSH facility staff health and safety plans are applicable to this study. Since there will be no laboratory activity associated with this research, laboratory health and safety plans are not applicable.

I. References

Dempsey, P.G., McGorry, R.W., and Maynard, W.S. (2005). A survey of tools and methods used by certified professional ergonomists. Applied Ergonomics, 36, 489-503.

Siegel, S. and Castellan, N.J. (1988). Nonparametric statistics for the behavioral sciences. New York: McGraw Hill.

Appendix A – Dempsey et al (2005) article – "A survey of tools and methods used by certified professional ergonomists".

Appendix B – Sample invitation e-mail to all eligible participants

Appendix C – Informed Consent Statement

Appendix D – Revised questionnaire instrument.

Appendix B – Sample invitation e-mail to all eligible participants

Dear _____:

We are writing to let you know about a survey of certified Ergonomics professionals that will be conducted by the U.S. National Institute for Occupational Safety and Health in the next few weeks. The purpose of the survey is to investigate what tools are most commonly used by practicing Ergonomists, and the frequency of use. Although there are many measurement and assessment approaches available, little formal feedback to the research community is available. Such feedback has the potential to inform the development of future tools and techniques. Practitioners can benefit as well, as the survey results will provide an opportunity to compare the tools you use to those used by a larger sample of Ergonomists.

A similar survey was conducted among Ergonomists practicing in the U.S. in 2004 by the Liberty Mutual Insurance Company. The upcoming survey represents a follow-up to that study and the study group will be broadened to include certified ergonomics professionals internationally. You are receiving this invitation to participate based on your certified credentials in the practice of Ergonomics through one of the several accredited organizations we have identified. You will be receiving information about how to complete the online survey in the next few weeks, and we hope you will take a few minutes to share your opinions with your fellow Ergonomists. Participation in this survey is, of course, completely voluntary.

We anticipate publishing the survey results in multiple formats, and we look forward to sharing these results openly.

Sincerely,

Brian D. Lowe, Ph.D., CPE
Patrick G. Dempsey, Ph.D., CPE

Appendix C – Informed Consent Statement

[This statement will appear when the respondent launches the web-site link. The survey can not be started unless the "Accept" button is clicked.]

Statement of Consent to Participate In Survey

If you agree to participate in this research, you will be asked to complete a survey with questions about tools and assessment methods used by professional ergonomists like yourself. The questionnaire should take about *30 minutes* to complete. There is no direct benefit to you from taking part in this study. This research is intended to improve our understanding of the use of various tools and assessment methods in the field of ergonomics related to the prevention of musculoskeletal disorders. We plan to report these findings in a peer-reviewed journal.

Your individual data will be handled as confidentially as possible. When results are reported, personally identifiable information will not be used. No personally identifying information will be collected through the web-based survey. The linkage of submitted questionnaire responses to individual identity is only accessible to the project Principal Investigator to assure the legitimacy of each respondent's certification. (We have only sent e-mail invitations to participate to ergonomists with professional certification in the United States, Canada, United Kingdom, Australia, and New Zealand.)

You will not be compensated for taking part in this survey. You are free to decline to participate and you can decline to answer any question(s) or stop taking part in the survey at any time. If you have any questions about this research, please feel free to contact Brian Lowe at the U.S. National Institute for Occupational Safety and Health (NIOSH): blowe@cdc.gov. If you have questions about your rights or treatment as a participant in this study, please contact the NIOSH Human Subjects Review Board Office at: cin-hsrb@cdc.gov.

By clicking the ACCEPT button below you are consenting to participate in this study.

◯ **ACCEPT** *[Respondent who click this option will continue to the questionnaire as participants.]*

◯ **DECLINE** *[Respondents who click here will receive the message "Thank you for your time and consideration given to participating." There will be no further action for them.]*