Work Should Not Hurt You: Reduction of Hazardous Exposures in Small Businesses Through a Community Health Worker Intervention

ClinicalTrials.gov ID NCT03455530

PI: Professor Paloma Beamer (University of Arizona)

Protocol

September 8, 2017

F200: Application for Human Research

PROJECT TITLE: **El Trabajo no te Debe Dañar: Reduction of Hazardous Exposures in Small Businesses through a Community Health Worker Intervention – R01ES028250**

INVESTIGATOR INFORMATION

Principal Investigator Name, Degree(s):	Paloma Beamer, PhD
Affiliation	☒ UA ☐ B–UMG
Principal Investigator **UA NetID**	pbeamer
Status/Rank:	Associate Professor
Center:	Community Environment & Policy
Department:	
College:	Public Health
Contact phone:	520-626-0006
Official Institutional Email:	pbeamer@email.arizona.edu

ADVISOR CONTACT INFORMATION (REQUIRED FOR ALL STUDENTS AND RESIDENTS)

Name, Degree(s), **UA NetID**:	
Contact phone:	
Official University Email:	

ALTERNATE/COORDINATOR or Co-PI CONTACT INFORMATION
***THIS INDIVIDUAL WILL RECEIVE COPIES OF ALL CORRESPONDENCE ON THE STUDY**

Name, **UA NetID**:	Nathan Lothrop; lothrop
Contact phone:	520-314-7971
Official University Email:	Lothrop@email.arizona.edu

SECTION 1: REQUIRED SIGNATURES

1. PRINCIPAL INVESTIGATOR

I will conduct my study according to the University of Arizona HSPP policies and procedures for research with human subjects.

Signature	Date	Print Name
Paloma Beamer	09/08/17	Paloma Beamer

2. ADVISOR (FOR ALL STUDENTS AND RESIDENTS ACTING AS THE PI)

I will oversee the student researcher according to the University of Arizona HSPP policies and procedures for research with human subjects.

Signature	Date	Print Name

3. SCIENTIFIC/SCHOLARLY REVIEW (SEE HSPP GUIDANCE ON REQUIREMENTS FOR SCIENTIFIC/SCHOLARLY ASSESSMENT - INCLUDE DOCUMENTATION FOR OPTIONS A AND B WITH SUBMISSION MATERIALS.)

a. ☒ Nationally based, federal funding organization (NIH, NSF) subject to full peer review

b. ☐ Nationally based, non-federal funding organization (March of Dimes, Amer Academy of Pediatrics) subject to peer review

c. ☐ Locally constituted peer review (signature required)

Signature	Date	Print Name

4. DEPARTMENT/CENTER/SECTION REVIEW

I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.

Signature	Date	Print Name/Email

5. RESPONSIBLE PHYSICIAN (PROJECTS INVOLVING MEDICAL PROCEDURES WHICH THE PI IS NOT AUTHORIZED TO CONDUCT)

I am a physician licensed by the State of Arizona (or US license for the SAVAHCS). I will be responsible for ensuring that all procedures that are part of this project and that require the attendance of a licensed physician will have a suitable physician present during the procedures. If at any time this is not possible, I will inform the IRB before any procedures are conducted.

Signature	Date	Print Name

SECTION 2: GENERAL INFORMATION

1. How many Human Research studies does the PI have open?
5

2. How many research staff will be involved in the Human Research?
6

3. What is the expected length of this project?
09/01/17-08/31/22

4. Will the University of Arizona be the coordinating center for a multi-site study?
☒ No ☐ Yes- Complete Appendix C- Multi-Site study

5. Retention of study materials before, during, and after completion of the project:

a. Where will original signed consent and PHI Authorization documents be stored (building name and room)? Location: Drachman A223

b. How long will consents be maintained after conclusion of the project?
☒ 6 years (UA standard) ☐ 6 years after child reaches 18 ☐ Other (explain):

6. Is or will the project be funded by an external funding source e? ☐ No ☒ Yes- Complete below:

a. Funding PI: Paloma Beamer, PhD
b. Proposal Title: El Trabajo no te Debe Dañar: Reduction of Hazardous Exposures in Small Businesses through a Community Health Worker Intervention – R01ES028250
c. Funder Name: NIH
d. Total funding amount **OR** per subject amount: $3,498,725.00
e. UAccess Account Information Provide one of the following below:
   i. Institutional Proposal #: 00753004
   ii. Award #:

Submit complete copy, cover-to-cover, of grant or award. If you need help locating any of the UAccess numbers please call Sponsored Projects at 626-6000.

7. Is the project funded by a **For-profit** industry sponsor? ☒ No ☐ Yes- Complete required below:

a. IRB Payment eDoc #:

*Please review **HSPP Guidance, Fees for Human Research**, for more information.*

8. Conflict of Interest (COI):
The Principal Investigator hereby affirms that ALL individuals who meet the definition of *investigator* for this project in the current *Policy on Investigator Conflict of Interest in Research* have completed the mandatory Conflict of Interest training and Disclosure of Significant Financial Interests.

☒ Yes ☐ No (explain):

9. Additional requirements:

Certain types of research require additional regulatory documentation. Please identify which of the following apply to your project. Complete the appropriate Appendix and submit as part of the submission materials.

☐ Appendix A – Children (subjects under 18)
☐ Appendix B – Drugs/Devices (A clinical investigation of a drug or device)
☐ Appendix C – Multi-Site study (The UA IRB will review research activities for an investigator or research staff not affiliated with the UA who is 'engaged in the research' (e.g. consenting, collecting data, or analyzing identifiable information)
☐ Appendix D – Pregnant Women/Neonates
☐ Appendix E – Prisoners
☐ Appendix F – Waivers of consent, waiver of a signature, or waiver or alteration of PHI
☐ Appendix G – Exception From Informed Consent (EFIC)
☐ Appendix H – Native American or International Indigenous populations
☒ None apply to the proposed study

10. Research Site: Small businesses in Tucson AZ

Location (Explain): Beauty salons and auto repair shops in 7 underserved zipcodes in Tucson, Arizona

If research is taking place at B–UMG or AZCC please check the appropriate boxes below:

Banner – University Medicine Group:

☐ Phoenix Campus	☐ Biological specimens	☐ Clinical Data
☐ Tucson Campus	☐ Biological specimens	☐ Clinical Data
☐ South Campus	☐ Biological specimens	☐ Clinical Data

**Submit a copy of the UAHS Research feasibility review approval*

University of Arizona Cancer Center:

☐ North Campus	☐ Biological specimens	☐ Clinical Data
☐ Orange Grove Clinics	☐ Biological specimens	☐ Clinical Data
☐ Phoenix	☐ Biological specimens	☐ Clinical Data

**Submit a copy of the Scientific Review Committee letter*

SECTION 3. PROJECT NARRATIVE

1) Background

This project aims to reduce negative health outcomes in small businesses that primarily employ high-risk Latino workers by characterizing their exposures to hazardous chemicals and assessing if a community health worker (CHW) intervention is effective at decreasing these exposures. Occupational disease and injury, though preventable by definition, are leading causes of death in the

United States, with a disproportionate burden faced by Latinos. Small businesses pose a particular risk. They are more likely to employ low-wage Latino workers, and often use hazardous solvents containing volatile organic chemicals that can cause asthma, cancer, cardiovascular, and neurological disease; yet their workers lack access to culturally and linguistically appropriate occupational health and pollution prevention information due to economic, physical, and social barriers. CHW-led interventions and outreach in Latino communities have documented increased access to health care and health education and reduced workplace exposures among farmworkers. CHWs are an innovative method to bridge the gap between these small business communities and other stakeholders. The proposed project will capitalize on established partnerships between the University of Arizona, the Sonora Environmental Research Institute, Inc. and the El Rio Community Health Center. A community-engaged research framework will be used to complete three specific aims: 1) Quantify and identify exposures to hazardous chemicals in the two high risk small business sectors common in our target area (i.e., auto repair shops and beauty salons); 2) Work collaboratively with business owners, trade groups, workers and CHWs to design an industrial hygiene-enhanced CHW intervention tailored for each small business sector; and 3) Conduct a cluster randomized trial to evaluate the effectiveness of the CHW intervention at reducing workplace exposures to volatile organic compounds and assess which factors led to successful utilization of exposure control strategies in both male and female-dominated businesses. Businesses will be randomized to either an intervention or delayed intervention group, both of which will receive incentives to participate, such as worksite health screenings. CHWs will work closely with business owners and employees to select and implement exposure-strategies appropriate for their worksite using a menu of complementary strategies of varying complexity and cost. This innovative project has the potential to directly reduce occupational health disparities through a CHW intervention that moves beyond providing occupational health education. The intervention will overcome current barriers by helping marginalized Latino workers and small business owners who may have limited education, literacy, and computer skills to understand the hazards associated with their work, and will empower them to have greater control over their occupational exposures, with the ultimate goal of preventing occupational disease and reducing health disparities.

2) Purpose

Project Goal: Determine if an industrial hygiene-enhanced community health worker (CHW) intervention can significantly reduce workplace exposures to hazardous chemicals in small businesses that mainly employ marginalized minority workers.

3) Lay Summary (approximately 400 words)

Occupational exposures contribute to minority health disparities. This study will formally evaluate if a community health worker intervention can effectively reduce workplace exposures to hazardous chemicals in marginalized small businesses. Through face-to-face encounters, this study will increase the capacity of workers with limited education, literacy, and computer skills to understand workplace hazards and implement effective control options to reduce exposures and prevent occupational disease.

For Aim 1, we will characterize exposure to volatile organic compounds (VOCs) in 20 local businesses (10 from each sector). We will measure this through two methods: 1) Summa Canisters, which are metal canisters to collect air that is analyzed for VOCs, will be placed in the workplace and will give an average air concentration over time, and 2) A small device, a photo-ionizing detector (PID) called

a ppbRAE3000, which records VOCs exposure levels in real-time, will be worn by workers or owner/managers who agree to participate. We will facilitate focus groups with workers (x4) and brief interviews with owner/managers (1/shop) to explore elements of the safety culture such as risk perception and attitudes towards health promotion and personal protection. In Aim 2, we will work with various business owners, trade groups, workers and CHWs to design and refine approaches that CHWs can take to reduce workplace VOCs exposures, specific for each business sector. In Aim 3, we will recruit participants from 120 businesses (60 from each sector) and evaluate how effective the CHW intervention is at reducing workplace exposures to VOCs by measuring total VOCs before and after the controls for VOC exposures recommended by CHWs are put in place. To help the CHWs determine the best recommendations for each shop, they will ask owners a series of questions and complete a shop audit. In addition, we will also ask questions of owners and employees about their ideas on health and wellness in the workplace and how they felt about the CHW recommendations in their shops. We will also conduct focus groups with ownersto investigate their ideas on the CHW recommendations.

4) Setting of the Human Research

Research will take place in underserved communities in Tucson, AZ in small businesses (<25 employees) that primarily employ high-risk Latino workers. We will focus on beauty salons and auto repair shops. For measuring chemicals in air for Aim 1, we will work with a total of 10 of each business type drawn from seven zip code areas in Tucson (total of 20 businesses). For the interviews with owners and focus groups with workers as part of Aim 1, we will recruit owners and workers from these same 20 businesses. Focus groups will be held in a non-business related, neutral location in the general area. Interviews will be held on site.

In Aim 3, we will measure chemicals in the same way but from 120 shops total (60 from each sector) from the same seven zip codes in Tucson. If it is not possible to recruit all the shops we need, we will amend this geographic recruitment area in the future. Surveys on health and wellness and the CHW recommendations for reducing exposures will be done at the workplace. Any questions asked to refine the exposure control recommendations will take place at work. Focus groups will be held in a non-business related, neutral location in the general area.

Potential businesses will have the project fully explained to them. If a business agrees to participate and the owner signs the site authorization form, we will describe the project to employees and provide them with individual Informed Consent Forms.

The project will capitalize on established partnerships between the University of Arizona, the Sonora Environmental Research Institute, Inc. and the El Rio Community Health Center. Our hope is that a CHW intervention will be shown to be effective at decreasing VOC exposures in these small business types.

5) Resources available to conduct the Human Research

Key personnel include:

Paloma I. Beamer, Ph.D. Principal Investigator

Dr. Beamer is an Associate Professor of Environmental Health Sciences in the Mel and Enid Zuckerman College of Public Health and Chemical & Environmental Engineering at the University of Arizona.

Scott Carvajal, Ph.D., MPH Co-Investigator

Dr. Carvajal is a Professor of Health Behavior and Health Promotion in the Mel and Enid Zuckerman College of Public Health and director of the CDC-funded Arizona Prevention Center at the University of Arizona.

Dean Billheimer, Ph.D. Co-Investigator

Dr. Billheimer is a Professor in the Department of Epidemiology and Biostatistics of the Mel and Enid Zuckerman College of Public Health at the University of Arizona.

Maia Ingram, MPH. Co-Investigator

Ms. Ingram is Program Director for Community-Based Evaluation Projects in the Health Promotion Sciences Department of the Mel and Enid Zuckerman College of Public Health at the University of Arizona.

Community collaborators include:

Sonora Environmental Research Institute, Inc. (SERI):

SERI will lead the community health worker intervention. They will be responsible for recruitment of businesses, aid in development of the intervention, serve as a liaison and implement the intervention by conducting at least three visits to each business. They will also assist in training, workshops, and results interpretation and dissemination.

El Rio Community Health Center:

El Rio will conduct interviews with owner/managers and focus groups with workers in Aim 1. El Rio will be responsible for conducting health screenings, wellness consultations, and follow-up health care referrals (during Aim 3). They will also aid in development of the intervention and dissemination of the results in the community.

6) Study Population

We anticipate that we will obtain personal exposure measurements from *up to 4* workers at 140 businesses (Aim 1 n=20; Aim 3 n=120), as well as conduct focus groups with owners/managers at each business (n=140). Thus, we anticipate that our total subject population could be *700* small business workers and owners. It is possible that at some businesses with <4 workers, we may obtain repeat measurements on different days to ensure that 4 full-shift exposure assessments are conducted at each business during each assessment. This would result in a lower number of participants in our study. We have assumed 3 workers per business (n=420) in calculation of our planned enrollment, in addition to the 140 business owners. We will make every attempt to measure the exposure of the same workers at each assessment. However, because of timing constraints, high worker turnover or staffing changes in the businesses, it is possible that different workers could be measured at each assessment, resulting in a possible total of 1520 (20 business*4 workers+120 businesses*4 workers*3 assessments) worker subjects, in addition to the 140 business owner participants.

Inclusion criteria include workers or owner/managers of small businesses over 18 years of age in the auto repair or beauty salon sectors in southern metropolitan Tucson, Arizona. Exclusion criteria include age less than 18 years or people not working in auto repair or beauty salon sectors.

7) Recruitment Methods and Consenting Process

a. Recruitment Process:

Businesses will be recruited with the assistance of SERI CHWs and the Tucson Hispanic Chamber of Commerce. The project will be described to the business owner/manager and if they agree to participate and sign the site authorization form, workers will be told about the project's overall goals of community health interventions leading to decreased exposure to potentially dangerous chemicals in their workplace. In Aim 1, we are recruiting 20 businesses so that we can obtain an idea of current baseline VOC exposure levels and work practices, as well as owner/manager and worker ideas about health and safety in the workplace via interviews and focus groups. These are small businesses and SERI CHWs typically go door-to-door and explain the project orally. In Aim 3, we will recruit 120 businesses using the same methods as developed in Aim 1.

In Aim 3, once the business owner/manager agrees for their business to participate and signs the site authorization, the owner/manager will be recruited into the study, allowing the study team to get information about their shop and work practices critical for choosing effective ways of reducing chemical exposures (see *Owner_Consent* document).

Once the business owner/manager is recruited, individual employees and the owner/manager (if they do similar activities as workers) will be recruited with the goal of measuring four full-shift exposures per business (see *AirSampling_Consent* document). In Aim 3, we will complete four full-shift exposures in three different visit periods for a total of 12 full-shift exposures per business.

If the small business does not have four workers that are willing to participate, multiple measurements may be taken on the same workers on multiple days. Employees and owner/managers will also be recruited to join focus groups and do interviews, respectively. However, since the shops participating in Aim 1 are not able to participate in the randomized control trial in Aim 3 (for statistical reasons), we will only work with businesses with enough potential participants to consent to complete monitoring for 4 work shifts for any part of Aim 1.

In Aim 3, after we recruit air sampling participants, we will also recruit owners/managers and employees to complete a survey on health and wellness in the workplace (see *WellnessSurvey_Consent* document). Owner/managers will be recruited for focus groups discussing ideas about CHW recommendations on reducing workplace VOC exposures (see *FocusGroup_Consent* document). We will recruit employees to complete a survey on ideas about CHW recommendations on reducing VOC exposures (see *PostInterventionQx_Consent* document).

b. Informed Consent:

Once the business owner agrees to participate, they will be provided with a site authorization letter to sign. SERI CHWs will describe in the language of choice (English or Spanish) the study in general and the small VOC measurement device the participants will be asked to wear. They will also describe the survey on health and wellness in the workplace (see *WellnessSurvey_Consent* document) to owner/managers and employees; the focus groups (see *FocusGroup_Consent*

document) to owners/managers; the survey on ideas about CHW recommendations on reducing VOC exposures (see *PostInterventionQx_Consent* document) to employees.

The Informed Consent Form (ICF) document for each study component (e.g. Air Sampling; Wellness Survey; Focus Group, etc.), in the language of subject's choice – Spanish or English, will then be read aloud to potential subjects (ensuring low-literacy participants have the same access to information and chance to ask questions). If an employee or owner/manager agrees to participate, they will be given a written ICF document and have the chance to ask questions. The ICF may be taken home to discuss with family members if they wish. Please note that immigration status will not be asked, discussed, or recorded at any point in this project.

8) Research procedures involved in the Human Research

During Aim 3, owner/managers will answer questions about their workplace and practices and complete a survey on ideas about CHW recommendations on reducing exposures (see *Owner_Consent* document). Owner/managers and employees will have the option to consent into any of the following: wearing an air sampler during their work shift (see *AirSampling_Consent* document); and/or a survey on health and wellness in the workplace (see *WellnessSurvey_Consent* document). Owner/managers also have the option to consent to a focus group on ideas about the CHW recommendations on reducing VOC exposures (see *FocusGroup_Consent* document). Employees will also have the option to consent to answering questions in survey format on ideas about CHW recommendations on reducing VOC exposures (see *PostInterventionQx_Consent* document).

For the business owner/manager completing the *Owner_Consent* document, they will be asked questions on: their background and demographics; their workplace and practices so as to help inform the VOC control recommendations; and their ideas about the CHW recommendations on reducing VOC exposures that were recommended in their shop.

For the owner/manager or employee completing the *AirSampling_Consent* document, they will be asked questions on their background and demographics. Participants of air monitoring will wear a small device called a photo-ionization detector (PID) attached to their clothing during the work shift. The PID can only obtain total VOC exposure levels, and it is not possible to distinguish exposures to individual VOCs if multiple VOCs are present. The PIDs will record at the parts per billion level and will record the total VOC level every 60 seconds. Please see device information included with this submission for more information on the PID. Results of the sampling will be returned to participants individually by a CHW, and then they will be asked a brief survey on how it went to get their results returned to them.

For the owner/manager or employee completing the *WellnessSurvey_Consent* document, they will be asked questions on their background and demographics and on health and wellness in the workplace. This will take place at the health screening visit.

For the owner/manager completing the *FocusGroup_Consent* document, they will be asked questions on their background and demographics and ideas about the CHW recommendations on reducing VOC exposures in their business. This focus group will be held outside of work hours at a non-work location. Conversations during focus groups and interviews will be audio recorded and notes will be taken on the dialogue.

For the employee completing the *PostInterventionQx_Consent* document, they will be asked questions on their background and demographics and ideas about the CHW recommendations on reducing VOC exposures in their business. This questionnaire will be done at work during work hours.

All shops will receive a different printed postcard every 1-2 months throughout the study in the preferred language of the owner/manager. These postcards will address what is a VOC; a thank you for signing up for the study; and then series of reminders about focus groups for owner/managers.

9) Cost to subjects

There will be no direct cost to subjects. The air monitoring portion in this study will not take any extra time, since the participant will only participate during their regular work shift. It may take a few minutes to put the equipment on (this was approved as part of Aim 1 and has not changed for Aim 3). These pieces of equipment are designed to be worn by workers with minimum interference of their work.

The wellness surveys, focus groups, and post-intervention questionnaire portions will take up approximately 10 minutes, 1.5 hours, and 10 minutes of each participant's time, respectively. This includes travel to an off-site location for a focus group.

Questions for the owner/manager that will help inform how to better reduce VOCs will take approximately 1 hour of the participant's time.

For owner/managers who participate in both wellness surveys, a focus group, and questions about the shop come up with more appropriate methods of reducing VOC exposures in the shop, it will take a total 3 hours.

For employees who participate in both wellness surveys and the post-intervention questionnaire, and it will take a total of 30 minutes.

10) Risks to subjects

There is no known risk involved with wearing the PID. If the subject finds its presence annoying or uncomfortable in any way, they may simply take it off. There are no anticipated risks to subjects from participating other than the risks they encounter daily completing their normal job tasks.

There is no known risk involved with participating in focus groups or any surveys/questionnaires.

Potential subjects may refuse to be enrolled in the research study even if the small business owner/manager that employs them has agreed to participate by signing the site authorization letter. This will be explained to both owners/managers and employees at the onset.

Within the worksite, workers will know which of the other workers are participating in the study because they will be wearing the monitors and the monitors will be visible. Owner/managers will not know if their workers participate in focus groups as these will be held off-site outside of work hours (Aim 1).

It is possible that participants may be concerned about participating in our study because of their legal immigration status or concern about compliance with occupational regulations.

Business owners may be concerned about letting their workers participate because of economic risks, potential liability, or possible reputational harm.

Study staff may also be exposed to VOCs while collecting data in the small businesses.

Our team has substantial experience conducting studies with Latino populations of mixed immigration status, and with utilizing protocols that effectively minimize risks while working with these populations. This includes: 1) not asking about immigration status; 2) obtaining a Certificate of Confidentiality from NIH; 3) orally reading Informed Consent Forms to participants in their preferred language; and 4) minimizing collection of identifiable and private data as much as possible. Further, to protect any potential economic risk or harm to the businesses, we will maintain confidentiality of the participating business and will not link exposure data with a business in any public setting.

11) Potential benefits to subjects and/or society

Potential direct benefits to the subjects include knowledge of their personal VOC exposures and reduced exposures to hazardous chemicals in the workplace. As VOCs emitted from small businesses are one of the primary sources of hazardous air pollutants in urban air, particularly in minority neighborhoods, by reducing exposures in these workplaces, we may also reduce neighborhood exposures to these chemicals. This could benefit workers and their families if they live nearby. In our previous work, we have demonstrated that regions of metropolitan Tucson that have the highest levels of hazardous air pollution and emissions from small businesses have higher than expected cases of childhood wheezing illnesses.

12) Provisions to protect the privacy of subjects and the confidentiality of data

a. **Protection of subject privacy:** There will be no personal identifiers (including business name) on any written materials used for exposure assessments, surveys, questionnaires, or other data collection instruments. Businesses will receive an alphanumeric code. During focus groups, participants will be asked to NOT use their names when speaking. We will not discuss or inquire about immigration status at any point during the study. Consent forms and the link between personal identifiers and subject codes will be kept separately from all other study material, in hardcopy form only, within a locked cabinet in Drachman Hall, room A223 at the University of Arizona. All contact information will be kept there until the study is complete. In order to facilitate scheduling of previously consented individuals for air sampling between the three organizations, we will store the link between the participant/business alphanumeric code and identifying information temporarily on UA Box Health, a HIPAA-compliant data storage system, until all visits for the business and its participants are completed (estimated 9 months).

b. **Protection of data confidentiality:** The primary protection against potential risks is a data security plan that includes physical, administrative, and technical aspects for confidentiality and privacy of the data, including personal identifiers. Of particular importance will be the appropriate training of CHWs, interviewers, and program evaluators in maintaining confidentiality and privacy of all data, in addition to their formal training from Collaborative Institutional Training Initiative (CITI). To assure total anonymity of businesses and subjects, alphanumeric codes will be used. Digitized data will be de-identified and stored in a HIPAA-

grade encrypted file storage system (e.g., REDCap). This will include audio recordings of interviews and focus groups, which will be uploaded directly in REDCap. During focus groups, we will ask subjects NOT to use their names. Transcribing of any sort will be completed in a sound-proof room (Medical Research Building, room 113i), with any transcriptions or audio files being uploaded directly into REDCap. Only study personnel as indicated on the VOTF will have access to this information, including audio recordings and transcriptions. Participants are free to withdraw from the study at any time with no penalties. This right will be explained to each participant as part of the informed consent procedure.

These protections should provide confidentiality to the businesses and reduce the risk of economic harm. Ultimately, we anticipate that businesses will participate because they value the health and wellbeing of their workers and would like to reduce their occupational exposures and help them improve their health. Other businesses are likely to self-select out and are not likely to agree to participate in the study.

13) Access to Private Information

c. **Access to medical records (HIPAA)**: N/A – medical records will not be accessed

d. **Access to educational records (FERPA):** N/A – educational records will not be accessed

e. **Access to employee records:** N/A – employee records will not be accessed

14) Subject compensation

Subjects in the air monitoring portion of Aim 1 will not be compensated for participation. Subjects in the focus groups portion and interviews of Aim 1 will be paid $25 cash for their participation.

In Aim 3, owner/managers participating in air sampling will be paid $10/shift, up to 3 shifts (a total of $30); owner/managers participating in focus groups will be paid $15. An owner/manager could be compensated up to $45 over the course of the study. Employees participating in air sampling will be $10/shift up to 5 shifts (a total of $50). An employee can be compensated up to $50 over the course of the study.

15) Medical care and compensation for injury

No risk of injury is anticipated due to study participation. However, in case of an injury, we do not have any monetary compensation to cover any possible costs related to the injury. Workers will be provided with referral to appropriate community health clinics for follow up if they are concerned about their exposures or any related findings.

16) Monitoring for subject safety

This research does not involve more than minimal risk to subjects. However, because our CHW intervention meets the NIH definition of a clinical trial, we have developed a Data and Safety Monitoring Plan. Data will be monitored by UA investigators not involved in the research, who have substantial experience in human exposure studies. Each data collector will complete a daily log

during the assessment periods, which will include reporting of any breaches of the interviewing process or exposure assessment or any adverse events as well as document instrument calibration. At least two of the following three investigators below will meet to review reports and logs on a quarterly basis to monitor data quality, recruitment, accrual, retention, VOC exposures, and maintaining data security. Data and safety monitoring meetings will be held in a conference room, adjacent to where the hard copies of the data and logs are maintained in locked storage. They will report any data or safety issues immediately to the project investigators and appropriate entities.

The following UA investigators have agreed to provide oversight on data and safety monitoring for this study:

- Jeff Burgess, MD, MS, MPH; Associate Dean of Research, Mel and Enid Zuckerman College of Public Health; Professor, Environmental Health Sciences, Mel and Enid Zuckerman College of Public Health
- Walter Klimecki, DVM, PhD; Interim Department Head and Associate Professor, Pharmacology & Toxicology, College of Pharmacy
- Philip Harber, MD, MPH; Professor, Environmental Health Sciences, Mel and Enid Zuckerman College of Public Health

In addition to these protections, project investigators will establish a set of exposure criteria that will be provided to research staff to determine if a workplace presents immediate, severe risk to workers and themselves. Research staff will be trained to call project investigators immediately, and together they will work with the business owners to resolve the issues with the appropriate regulatory and health agencies.

17) Withdrawal of subjects

Subjects may withdraw themselves from the study at any time they wish. Any data collected about chemicals in the air or the subject's views on safety and health in the workplace from focus groups or interviews to that point may be used in this study. The voluntary nature of their participation will be made clear during the consenting process.

Subjects would be withdrawn from the study if it were deemed by any expert on the study team to be in the participant's best interest to withdraw.

18) Sharing of results with subjects

Air monitoring participants will be provided with the results of their exposure assessments and an interpretation of these exposures with respect to activities at the business, as well as any relevant recommendations on how to reduce their exposures. Participants will be referred to appropriate community health clinics for follow up if they are concerned about their exposures.

Owner/managers will be provided the same results materials as given to all air monitoring participants. In doing so, we realize that owner/managers may be able to identify which results correspond to which worker; however, this will be a condition that air monitoring participants will agree to during consenting.

These results will be provided by the CHWs in person, so subjects can ask questions. CHWs will be provided with a list of experts, including the PI and co-investigators, who will be able to provide on-site technical advice to businesses seeking assistance with designing and implementing their control

plans. These experts will be assembled from five UA colleges and include industrial hygienists, engineers, toxicologists, and occupational doctors.

19) Future use and long-term storage of data or specimens

Personal information we get from Aim 3 will not be stored for future research. We will use the data (not personal information) from this study for future research.

20) Information management

N/A

21) Clinical Trials.gov Information

☒ ClinicalTrials.gov "NCT" number for this trial (provide): NCT03455530
☐ Registration pending
☐ Clinical trial does not require registration (explain):

22) Gases

N/A

SECTION 4: LIST OF ATTACHMENTS FOR THIS SUBMISSION (REQUIRED) (Items listed here are expected to be attached as separate documents. These documents will appear in the UA HSPP IRB approval letter as 'documents submitted concurrently' with the review.)

Document Name	Version Date
1. Research_Personnel_List_10	**1.** 10/17/19
2. SiteAuthorization	**2.** 10/17/19
3. RecruitmentPoster	**3.** 11/11/19
4. ParticipantInfoForm	**4.** 10/17/19
5. ParticipantBackgroundDemographics	**5.** 10/17/19
6. SERI_PreAssessment_SPN	**6.** 10/17/19
7. SERI_PreAssessment_ENG	**7.** 10/17/19
8. SERI_Assessment_SPN	**8.** 10/17/19
9. SERI_Assessment_ENG	**9.** 10/17/19
10. Site_Authorization_ENG	**10.** 10/17/19
11. PostInterventionQx_ENG	**11.** 10/17/19
12. PostInterventionQx_SPN	**12.** 10/17/19
13. FocusGroup_Questions_ENG	**13.** 11/11/19
14. FocusGroup_Questions_SPN	**14.** 11/11/19
15. WellnessSurvey_ENG	**15.** 10/17/19
16. WellnessSurvey_SPN	**16.** 10/17/19
17. AirSampling_Consent_ENG	**17.** 11/11/19
18. AirSampling_Consent_SPN	**18.** 11/11/19
19. WellnessSurvey_Consent_ENG	**19.** 10/17/19
20. WellnessSurvey_Consent_SPN	**20.** 10/17/19

21. FocusGroup_Consent_ENG	**21.** 11/11/19
22. FocusGroup_Consent_SPN	**22.** 11/11/19
23. Owner_Consent_ENG	**23.** 10/17/19
24. Owner_Consent_SPN	**24.** 10/17/19
25. PostInterventionQx_Consent_ENG	**25.** 10/17/19
26. PostInterventionQx_Consent_SPN	**26.** 10/17/19
27. Postcards	**27.** 10/17/19
28. HealthScreeningFlyer	**28.** 11/11/19
29. UA_SiteAudit_Auto	**29.** 10/17/19
30. UA_SiteAudit_Beauty	**30.** 10/17/19
31. F200	**31.** 11/11/19
32. AirSampling_Script_ENG	**32.** 11/11/19
33. AirSampling_Script_SPN	**33.** 11/11/19
34. FocusGroup_Script_ENG	**34.** 11/11/19
35. FocusGroup_Script_SPN	**35.** 11/11/19
36. PostInterventionQx_ENG	**36.** 11/11/19
37. PostInterventionQx_SPN	**37.** 11/11/19
38. WellnessSurvey_Script_ENG	**38.** 11/11/19
39. WellnessSurvey_Script_SPN	**39.** 11/11/19

See HSPP website for submission requirements.

Items needed for approval:

- Word Versions of Application, Consents, Recruitment and Data Collection
- **F107: Verification of Training Form**
- **Current PI/Co-PI CVs or biosketch**, if not included with copy of grant application
- **Informed Consent/Permission/Assent Form(s)** – including study specific release of information documents, DHHS approved sample consent forms. If consent will not be documented in writing, a script of information to be provided orally to subjects

Other Items as applicable:

- **Appendix A - Children**
- **Appendix B - Drug/Device**
- **Appendix C- Multi Site Research**
- **Appendix D- Pregnant Women and Neonates**
- **Appendix E- Prisoners**
- **Appendix F- Waiver of Consent/ PHI**
- **Appendix G- Exception from Informed Consent (EFIC)**
- **Appendix H- Native American**
- **Biosafety Review letter** (for UA - Institutional Biosafety Committee)
- **Certificate of Confidentiality**
- **Compressed Gases Review letter** (for UA – Research Instrumentation)
- **Contract** – complete or draft copy of contract including budget
- **Data Collection Tools** – surveys, questionnaires, diaries not included in the protocol, data abstraction form for records review
- **Data Monitoring Charter and Plan**
- **Drug/Device information** – Investigator's Brochure, drug product sheet, device manual, user's manual, instructions for use, package insert, IND/IDE documentation, FDA 1572 form, 510k indication, FDA exemption, sponsor determination of device risk, etc.
- **Export Control Review**

- **Grant Application(s)** – cover-to-cover copy of grant, regardless of home institution or funding agency, and a copy of the Notice of Grant Award.
- **Multi-site information** (for sites engaged in research where the UA is the IRB of record)
  - Copy of any approvals granted from that site (including determinations if this site has an IRB of its own)
  - Site-specific F107
  - Copy of the site's human subjects training policy
  - CV and medical license (if applicable) of site PI
- **Other Approval letters** (e.g., school districts, Tribal, other IRB approvals)
- **Participant Materials** – written materials to be provided to or meant to be seen or heard by subjects (e.g. study newsletter, physician to participant letter, wallet cards, incentive items, holiday/birthday cards, certificates, instructional videos/written guides, calendars, certification of achievement, etc.)
- **Payer coverage analysis**
- **PHI Authorization Form(s)**
- **Protocol** – including all amendments/revisions, sub- or extension-studies
- **Radiation Safety Review** letter- needed regardless if the radiation device is approved and used standard of care
- **Recruitment Materials** – telephone scripts, flyers, brochures, websites, email texts, radio/television spots, newspaper advertisements, press releases, etc.
- **Scientific Review Committee** letter (for cancer related projects – AZCC SRC; other units as applicable if the unit has a scientific review committee)
- **Site Authorizations** for research purposes and/or access to administrative records/samples
  - External sites (such as schools, other hospitals or campuses, etc.)
  - UAHS Research Portal feasibility review approval
- **Travel Authorization documentation** (for UA – Office of Global Initiatives)
- **Use of retrospective research samples and/or data** – IRB approval letter, original consent under which samples/data were collected, letter allowing access to samples