Human Research Protection Program
Institutional Review Board
Office of Research Integrity
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IRB@oregonstate.edu | http://research.oregonstate.edu/irb

RESEARCH PROTOCOL

November 2020

1. **Protocol Title**: Passive sampling wristbands as a measure of chemical exposure

PERSONNEL

2. **Principal Investigator**: Kim Anderson, PhD
3. **Co-investigator:** Diana Rohlman, PhD
4. **Investigator Qualifications**

   Anderson: PhD in Chemistry, developed silicone wrist bands; Rohlman: PhD in Toxicology, experienced with community-engaged research and data dissemination using the wristbands

5. **Training and Oversight**

   The PI will oversee and be responsible for the conduct of the study with the assistance of the Co-Is. The PI and co-PI will correspond and meet as needed with study staff and collaborators to ensure each study team member understands their role and to ensure adherence to the protocol. All study staff will have received human subjects ethics training, and those who will have direct contact with study participants are experienced in handling confidentiality, privacy, and informed consent requirements.

6. **Conflict of Interest**

   The research detailed in this proposal may be related to MyExposome or its activities and could potentially be influenced by the investigator's interest. The PI and co-PI (Anderson, Rohlman) either own or are related to someone who owns MyExposome Inc. As a result, there is potential for MyExposome and these researchers through their relationship with MyExposome to financially benefit from the outcomes of the research. In order to manage the potential for the research to be affected by this, the University and the researchers have a plan to address it. In accordance with the management plan, Anderson and Rohlman will disclose financial interests in MyExposome, Inc to subjects and other appropriate parties.

FUNDING

7. **Sources of Support for this project (unfunded, pending, or awarded)**
   Sources of support for the project are unknown at this time. The research protocol will be initiated in response to time-dependent issues (i.e. disasters). The protocol will only be initiated as it pertains to the use of the passive wristband sampler. However, potential sources of funding include the OSU Environmental Health Sciences Center and the National Institutes of Health (NIH), National Institute of Environmental Health Sciences (NIEHS).

DESCRIPTION OF RESEARCH

8. **Description of Research**

The overall goal of this project is to use the passive wristband sampler to evaluate personal chemical exposure either following disasters, or for emerging environmental health concerns. Chemical exposures measured by the wristband include volatile and semi-volatile organic compounds. The passive wristband sampler is a low-cost, maintenance-free easy to use sampler. This Research Protocol submitted to the OSU Institutional Review Board is a unique application as it seeks to obtain pre-approval on a research protocol which can be quickly revised and approved based on certain initiating events. These initiating events will be specific to chemical releases that can be evaluated and measured with the passive wristband sampler. Examples include: Forest fires, oil spills (on land and water), baseline sampling in areas with high rates of oil spills, coal train derailments and other events that may result in combustion.

The goal of this project is to develop a 'blanket' IRB with recruitment cards (Anderson_recruitment cards) and research explanation cards (Anderson_verbal consent guide; Anderson_assent guide) that can be used in a variety of scenarios (described below in Background Justification). These materials can be easily modified as needed to include: (1) rationale for sampling; (2) researchers and student staff involved; (3) inclusion/exclusion criteria and; (4) incentives, as appropriate.

Data from this project may be used with environmental research, using passive air, soil, water and sediment samplers. These samplers may be deployed on public or private (with permission) land or in public or private buildings/residences. Where these environmental samplers are used *in combination* with wristband sampling, consent forms will be amended to include the use of an environmental sampler. An example of this scenario is: When performing research around wild-fire smoke exposure, participants may be asked to wear a wristband *and* place a stationary air sampler on their property or in their home.

The intended uses for this research are for publication and presentation.

9. Background Justification

The passive wristband sampler is designed to be rapidly deployed following an initiating event or to improve research around emerging environmental hazards, such as hydraulic fumes on aircraft. For example, in the summer of 2016 an oil train derailed, spilling oil into the Columbia River and contaminating ground water in Mosier, OR with volatile and semi-volatile organic compounds. Dr. Anderson was able to rapidly deploy environmental samplers, to include sediment pore-water samplers within days of the spill. The ability to pair environmental samplers with personal samplers such as the passive wristband sampler allows researchers to identify human health risks that may be posed by environmental disasters such as the Mosier oil spill. Specifically, appropriate and timely research can characterize environmental contaminants, determine exposure to environmental contaminants among vulnerable populations and disaster responders, evaluate effectiveness of interventions, and determine short- and long-term health consequences of the disaster. However, disasters present unique challenges to conducting scientific research including funding, identifying appropriate research questions, and understanding concerns of affected communities among others.

10. Multi-center Study

At this time, OSU is the only institution conducting this study. Given the nature of disasters, additional sites for the project are unknown at this time. The protocol will be initiated in response to a disaster, wherein passive wristband samplers would be appropriate to evaluate personal exposures to chemicals. As such, the occurrence is unknown.

We will provide the information requested below once partners are identified after the disaster occurs. In addition, we will provide documentation of human subjects training for all members of research team from other institutions and agencies.

a) *Name and Federal Wide Assurance (FWA) number of each participating institution:*
b) *Contact name and information for IRB of record at each participating institution:*
c) *Contact name and information for the Investigator(s) at each participating institution:*
d) *Role of each participating institution (e.g., recruitment, sample/data collection, sample/data analysis, etc.):*
e) *Method for assuring all participating facilities have the most current version of the protocol:*
f) *Method for confirming that all amendments and modifications in the protocol have been communicated to participating sites:*
g) *Method for communicating to participating facilities any serious adverse events and unanticipated problems involving risks to subjects or others:*
h) *Method of communicating regularly with participating sites about study events:*
i) *Approval letters from all of the IRBs of record for all participating sites (or indicate that they are pending and provide upon receipt):*
j) *Confirm that the PI at OSU will maintain documentation of all correspondence between participating sites and their IRBs of record:*

11. External Research or Recruitment Site(s)

External research and recruitment sites are unknown at this time. Research protocol will be initiated in response to a disaster and, due to the nature of the event, the occurrence is unknown. However, we plan to engage community partners for *recruitment* due to the nature of events we are investigating. Partnering with trusted community groups will be vital to the success of any research project initiated in response to a disaster. Potential partners for recruitment include local health departments, hospitals, clinics, non-profits and other community groups.

We will provide the information requested below once partners are identified after the disaster occurs. Importantly, if community groups include Tribal Populations, we will include the information listed in *f-h*:

a) *Name or description of each research site:*
b) *Name and role of appropriate authority from each site providing a letter of support or permission (when applicable):*
c) *Name of each recruitment site:*
d) *If recruitment method involves more than an advertisement (newspaper classified, flier, listserv email), name and role of appropriate authority from each site providing a letter of support:*
e) *Attach or include ad copy or correspondence to be used for recruitment*
f) *Tribal Populations: letter of support from the appropriate point of contact, i.e. Tribal Senate, Board of Trustees, etc.*
g) *Tribal Populations: Copy of IRB submitted to Tribal IRB (i.e. Northwest Indian College, NW Portland Area Indian Health Board, Tribe-specific IRB)*
h) *Tribal Populations: Copy of pertinent Data and Material Sharing and Ownership Agreement*

12. Subject Population

Participant characteristics: Study participants include individuals impacted by a disaster (natural or man-made). Study population will not be limited to a specific ethnic or gender group. Furthermore,

following the recommendations of Packenham et al. (2017) children will be eligible to participate as appropriate. Requirements for parental consent and assent from children vary by state; however, the 18 years is the threshold for all states except Alabama (19 years), Nebraska (19 years or married), Mississippi (21 years), and Puerto Rico (21 years). Specific study populations will be determined once the disaster occurs, but potential study populations include but are not limited to general community members, first responders, healthcare workers, disaster relief volunteers, National Guard, etc. Researchers and student researchers will also be included within the study population (study team member). The justification for including study team members is as follows: In the wake of a disaster or in the face of emerging contaminants, there are often significant environmental concerns, such as soil, water, air and groundwater contamination. Research team members may be deploying these environmental samplers and as a result, would be considered initial responders that can wear wristband samplers.

Total target enrollment number: 1500. Enrollments will be specific to the nature of the event and subsequent research questions to be addressed. We will work with the IRB office to increase enrollment should this be necessary.

Description of any vulnerable population(s): No vulnerable populations will be targeted for this project. However, vulnerable populations such as pregnant women, children, non-English speakers, and non-literate participants will be able to participate. However, researchers acknowledge that all members of a population impacted by a disaster may be considered vulnerable and extra steps will be taken during the consent and assent process to ensure that participants willingly and knowingly agree to participate. Adults lacking capacity to participate are ineligible to participate.

Inclusion criteria: Adults and children of any gender, ethnicity or race. Additional inclusion criteria will be determined at a later date and will be relevant to the environmental exposure(s) under examination.

Exclusion criteria: Adults lacking capacity to participate. Additional exclusion criteria will be determined at a later date and will be relevant to the environmental exposure(s) under examination. For example, a study assessing inhaled PAH exposure in wildland fire fighters may exclude smokers.

Recruitment:

Researchers will, in advance of the event or quickly after the disaster, identify local partners to assist with recruitment. Potential partners for recruitment include local health departments, hospitals, clinics, non-profits and other community groups. Recruitment processes will vary depending on the research methods to be utilized but will be guided by potential participants' ability to participate. For community members at large of areas impacted by disasters, recruitment will proceed in close collaboration with community partners and will occur largely in-person but may also occur via telephone or electronically when data collection occurs online (e.g. online survey). For local or regional disasters, we plan to use existing relationships with the state health department (Oregon Health Authority), local health departments, local emergency managers *before* the disaster occurs to plan recruitment of study populations. We will recruit first responders (when appropriate) by identifying groups representing them *before* the disaster occurs as well.

Regardless of the recruitment method, confidentiality will be ensured by not recording any personal identifiers on data collection instruments. Rather, identification numbers will be generated for all potential participants and will be used on all hard copies and electronic forms of data. The key linking participants to their data will be kept separately on the secure desktop

computer of the PI or a Co-I. If participants are dual-enrolled in this project and IRB #7927, a list of linked codes and identification will be kept, available only to the PI and Co-I.

Any advertisements and recruitment materials will be submitted to the IRB for approval before they are disseminated.

Participants may be eligible for an incentive to participate comensurate with the level of participation.

13. Consent Process

Waiver of documentation A waiver of documentation of informed consent is requested. Recruitment is expected to occur quickly in the event of a disaster or emerging contaminant, and to be less of a burden to first responders or other occupational groups who may worry that their information could be disclosed to their employers. To ensure rapid response, we request a waiver of documentation. Interested participants will be given information about the study (See Anderson_recruitment cards) prior to determining if they would like to participate. If collaborators from other institutions will assist with recruitment and data collection, site-specific contact information may be provided to participants at the discretion of the participating institutions.

Describe where and when consent will be obtained. Location of where informed consent will be obtained will vary depending on the nature of the project. However, research staff will ensure that informed consent is obtained in a location such as a private or semi-private room in a community center, local health department, participant's home, etc. Steps will be taken to ensure privacy of the interaction between participants and research staff.

Obtaining consent online. Online recruitment may be used in the project. Updated recruitment materials will be provided to IRB prior to use. Participants will confirm that they meet the inclusion and exclusion criteria and an explicit statement acknowledging consent to participate will be provided to the participant which he/she will respond in the affirmative to proceed. Parents or legal guardians must complete the enrollment process with their child.

Contact information for research staff (e.g. dedicated email address) will be provided should the participant have questions or concerns about the project.

Assessment of comprehension. When consent is obtained in-person, comprehension of consent information will be assessed after the member of research team has read the consent form to the participant. The staff member will ask the participant to state in his/her own words the objective(s) of the study. Data collection will proceed if the participant is able to convey the study objective(s) to the research staff member. When consent is obtained online, the participant will be asked to answer several questions regarding the study objectives and their role as a participant.

Children. Per the recommendations of Packenham et al. 2017, children are eligible to participate. Oral consent must be obtained by at least one (1) parent or legal guardian (see 8146-Anderson_verbal consent guide_parent with child(ren)). Researchers will note in their field notes that consent was obtained from a parent or legal guardian to enroll the child into the research study. Children must also verbally assent (see 8146_Anderson_Assent Guide).

Non-English speakers. Non-English speakers may be targeted for inclusion and may participate in the study. As appropriate, bilingual and bicultural research staff will be employed to recruit and collect data from participants who do not speak English. Consent materials will also be provided in languages other than English. We will use a professional service to translate consent and other study

materials into participants' preferred languages, when appropriate. These materials will be approved by IRB prior to use. Researchers may identify translators or interpreters to assist with obtaining verbal consent and collecting data verbally. Participants will be provided with contact information translated into the appropriate language.

Significant new findings. No "new" findings are anticipated in any potential project stemming from this protocol. No interventions will be administered; therefore, there are no negative affects that will be unforseen at the beginning of the study**.**

Adult subjects with diminished capacity to consent. N/A per inclusion criteria and assessment of comprehension (above).

14. Assent Process

For studies involving children, oral assent from a parent or legal guardian will be obtained. Children age 4 and younger are ineligible to participate, due to potential safety concerns for this age group, including but not limited to choking hazards and possible problems related to circulation in extremities. Specific assent cards (similar to the consent cards) will be used as a guide for enrollment of children. The study will be described to both the child and the parent/legal guardian. For young children (5-7), a verbal process describing the study (as described on the written assent form) will be conducted and the child will be asked several questions regarding the study objectives and their role as a participant. For older children (8-17 years old), they may be provided a written assent guide (8146_Anderson_Assent) to review. Similarly, they will be asked questions regarding the study objectives and their role as a participant. If the parent/legal guardian consents and the child assents (verbal acceptance must be given by both), they may be enrolled. The researcher will note that parent/legal guardian consent was obtained along with verbal assent from the child. If the child reaches the legal age of consent (age 18 years) during the study, they will be contacted independently to provide consent.

15. Eligibility Screening

We will determine eligibility of prospective participants before obtaining informed consent by providing them with a list of eligibility criteria (in-person, via telephone, or via online) and asking if they are eligible and if they still interested in participating. Note that additional inclusion criteria may be generated depending on the nature of the specific study.

16. Methods and Procedures

As previously described, the proposed project will employ the passive wristband sampler. During enrollment, a short (under 30 minutes to complete) questionnaire will be administered (8146_Anderson_Questionnaire).

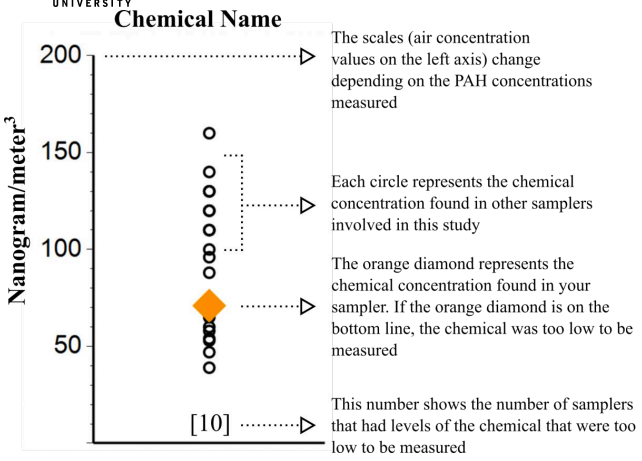
Personal samplers

The personal wristband sampler may be worn by participants to deterine exposure to environental contaminants as a result of a disaster. The passive wristband sampler can be worn as a wristband, or can be configured to look like a small badge. The two configurations are shown in this image. Dr. Kim Anderson, a chemist and Professor of Environmental and Molecular Toxicology at Oregon State University, has developed inexpensive personal samplers that can sequester thousands of bioavailable vapor-phase chemicals. These samplers sequester not only chemicals in commerce but also organic compounds formed during natural or industrial processes. Dr. Anderson fabricates samplers and extracts compounds from them via green chemistry, without carcinogenic solvents. Participants may be asked to wear a silcone passive sampler in the form of a wristband to determine exposure to environmental contaminants. These silicone wristbands are passive samplers that absorb volatile chemicals in the air. Length of time to wear the wristband will vary depending on the nature of the study. After use in the study, wristbands will be returned to research staff in prepaid packaging supplied to participants. In addition to the wristbands, researchers will utilize different samplers when appropriate (i.e. badges and small pieces of equipment).

Referrals

Researchers may encounter potential study participants who are in need of immediate assistance for themselves or their property. Given the immediate goal post-disaster is for the health and safety of affected populations, we will make appropriate referrals as needed. We will have contact information for the American Red Cross, Federal Emergency Management Agency (FEMA), local public health and law enforcement agencies, hospitals/clinics, etc.

Reporting data to participants: For participants that requested their data, short (less than 10 pgs) reports will be generated by the research team. For children enrolled in the study, the parent/legal guardian will have the option of requesting their child's data, and the data will be returned to the parent/legal guardian in care of the child. All data will be provided with appropriate contextual data (see below). Chemical exposure data will be reported back in the context of the study population. The individual will be able to see their level of exposure for a particular chemical shown in a display with all comparable levels of exposure of other study participants. This method of displaying the data in context has been utilized before (Brody et al. 2007) and is recommended for use when national standards, such as NHANES or the CDC National Report on Household Exposures, do not encompass the chemicals being studied. This sample graph, following the guidelines of Brody et al. 2007, is an example of how data can be presented within the context of the study population:



Follow-up questionnaires & surveys: Where appropriate, participants may receive follow-up surveys 1 week – 1 year following the study. Surveys will be administered on paper or electronically (using Qualtrics). Participants have the option to decline any and all surveys. Electronic surveys will include the option to unsubscribe from any further surveys. Paper surveys will be available on request or at in-person events wherein participation is voluntary. Example: A community event wherein aggregate data only (no individual data) is presented. Participants have the option of filling out a survey regarding the presentation of the data, their comprehension of the data, and the usefulness of the data. Please see 8146_Anderson_Evaluation_Questionnaires_Surveys. Other questionnaires may be administered to participants to evaluate: i) adherence to study protocol (i.e. wearing the wristband for the appropriate amount of time) and; ii) evaluation of their individual results. These questionnaires will be administered electronically; an email invitation will be sent requesting participants complete the survey (8146_Anderson_Questionnaire email text_10222018). A reminder email will be sent out two weeks later, with a final email sent one week before the questionnaire is closed (3 emails total). Each email will include an option for participants to stop receiving these requests. If a participant selects that option, they will be removed from all future questionnaires and surveys unless they contact a researcher and request to begin receiving emails again.

17. Compensation

If compensation is available for participants that agree to participate in the project, this will be listed in the consent form and will be provided to IRB prior to enrollment or data collection. Given the uncertain nature of disasters, it is unclear if funding would be available for participant incentives.

- Disaster response to Hurricane Harvey in Texas: Individuals will receive a $10 gift card upon enrollment, and a $20 gift card upon completion of the study.

18. Costs

There are no foreseen costs to participation.

19. Drugs or Biologics

Not applicable

20. Dietary Supplements or Food

Not applicable

21. Medical Devices

The wristbands that will be utilized in this study are not medical devices, as defined by the FDA. The wristbands are not intended for use in the diagnosis, treatment, or prevention of disease. They do not affect the structure or function of the body. The wristbands are inert devices that capture chemicals that are present in a person's environment.

22. Radiation

Not applicable

23. Biological Samples

Not applicable

24. Anonymity or Confidentiality

All research records will be handled as confidentially as possible and retained for at least 3 years post-study termination. Computer records will be protected by passwords and stored on an encrypted OSU server. All paper study records will be kept in a locked cabinet in a locked room accessible only to the study team.

Direct identifiers (name, mailing address, email and phone number) will be collected to be able to contact the participant throughout the course of the study, if needed. Study ID numbers will be generated corresponding to study participants and will be used for all types of data collected. Study ID numbers will be generated consistent wit the specific research study. Possible system includes study site and number (e.g. Corvallis0001).The key linking the study ID numbers to study participants identity will be stored separately from the study data on a secure server accessible only to senior investigators. In addition, linked list of study identifiers and information will be kept, accessible only to the PI and Co-PI, for participants that enroll in this project and IRB #7927.

At the completion of the data analysis of the study, only coded sample data will be kept. At this time, any information linking individual identifiers to subject codes will be shredded and destroyed.

No materials containing ID code and personal identifiers will be provided to anyone outside the research team. No individual identities will be used in reports or publications resulting from this study.

We will confirm that any information stored on computers will include systems that have fully patched operating systems and applications, current antivirus software with current virus definitions, consistent with all OSU Community Network updates.

For the Hurricane Harvey disaster response, data may be shared with participating institutions. We will utilize similar data security measures as described above. OSU may receive data from participating collaborators, but all data will be coded with study ID numbers, and personally identifiable information will not be included. Data will be transferred using OSU-licensed cloud-based servers.

25. Risks

We describe potential risks below by type of data which could be collected:

Personal sampling device: There is minimal risk associated with the wearing a personal sampling device of slight physical discomfort from the size or weight of the device.

Reporting data back to participants: We cannot guarantee the confidentiality of data reported back

to participants or the risk of harm in the form of concern or fear. However, it has been shown that benefit can be derived from knowledge, even when exposure limits are not certain and that the "right to know" is long established in environmental and occupational exposure settings. If a participant asks to receive their study results, we potentially would cause more concern withholding their data and restricting their right to know. Reports will be generated following published best practices in ethical data disclosure. Data will be presented confidentially, yet within the context of the study population. I.e. all data points will be monochrome, yet the individual's specific data will be colored. This data will not be available to anyone outside the study team or the participants, and will not be shared with any external entities until such time as it is publically available (i.e. presentation/publication/aggregate data presented at community meeting). Participants will be asked if they want to receive their data report to minimize risk of concern.

Follow up questionnaires/surveys: We will utilize either paper or Qualtrics surveys. Paper surveys will be stored in a locked file cabinet in the PI or co-PI's office. The documentation linking subject IDs and participant names will be safely kept in either paper or electronic form that is only accessible to those who need to know with a key or password. All files will be password protected and stored on secured Oregon State University servers and maintained for 3 years post-study termination.

Confidentiality/anonymity: While the risk of breach of confidentiality is low, there is a possibility of the disclosure of sensitive or personal identifying information. To minimize this risk the following confidentiality measures will be taken for all of the previously described methods of data collection. Only the minimum necessary participant identifiers and sensitive information will be collected. Subject IDs will be used to mark information when it is not able to be collected anonymously. The documentation linking subject IDs and participant names will be safely kept in either paper or electronic form that is only accessible to those who need to know with a key or password. All files will be password protected and stored on secured Oregon State University servers and maintained for 3 years post-study termination.

We will report any significant or unexpected adverse events to the appropriate entities in accordance with policy.

26. Benefits

In some instances, personal and community exposure measurements from disaster-related environmental experiences may be shared with participants. The attainment of knowledge related to disaster exposures can be considered an immediate benefit of participation. The long term benefit of participation is the contribution of knowledge to aid in the development of future interventions that can reduce disaster-related exposures and associated adverse short- and long-term health effects.

Benefits to willing participants receiving their data report have been noted in environmental health literature and improves community education on environmental health and air quality. As discussed by Brody et al. (2014), communication of results could increase beneficence as it gives participants "opportunities to learn about the strengths and weaknesses of the science in order to make their own decisions about their results, and autonomy and justice also reinforce the participant's right-to-know their results in order to act on them (Brody et al. 2007). For example, participants may choose to reduce exposures they have control over as a precaution or to become engaged in public discourse about chemical use and regulation." Additional studies have found that participants report

benefit from receiving their results even when exposure limits and human health effects remain uncertain (Adams et al. 2011; Morello-Frosch et al. 2009; Quandt et al, 2004). All participants will be directed to online resources and information on volatile and semi-volatile organic compounds, to include polycyclic aromatic hydrocarbons (PAHs), provided by Oregon State University's Superfund Research Translation Core, whose focus is on science communication of PAH exposures and health effects. A website is dedicated to this with the latest research and information. All about PAHs: http://superfund.oregonstate.edu/feature-story/all-about-pahs. Additional information about reducing exposure to common air pollutants will be provided via a simple infographic: https://superfund.oregonstate.edu/sites/superfund.oregonstate.edu/files/image-album/infographics/infographics.jpg

27. Assessment of the risks and benefits.

This study involves minimal risk with potential important benefit to society; therefore, the potential knowledge gained for society outweighs the risk to individuals.

References

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