Attachment D2
Consent Form

CDC NIOSH The National Institute for Occupational Safety and Health

Consent to be in a NIOSH Health Hazard Evaluation

(RETAINED SPECIMENS) Insert title of the study here

1	**Who is conducting the study?**	NIOSH is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC). NIOSH's Health Hazard Evaluation (HHE) Program conducts worksite investigations.
2	**What is the purpose?**	*This health hazard evaluation was requested by (requestor) because of (reported illness/exposures). The purpose of this evaluation is to measure exposures in the work environment, test for _____, and identify potential health effects from exposure to _____.*
3	**What will I do?**	*Briefly explain, in terms participants will understand, the tasks, procedures, therapies, tests, etc., involved in the HHE. You can use bullets. You can provide separate information sheets for complex or varied procedures. Inform participants if you will be recording images, or videos of them.* A. You will fill out a questionnaire about your work history, certain medical conditions, and symptoms you have when working around _____, (including any sensitive topics). *Either* [the questionnaire will be administered by a NIOSH representative] *or* [You will be asked to complete the questionnaire yourself, but a NIOSH representative will (be present to) (assist you and) check it for completeness (when you return it).] It should take from __ to __ minutes. B. You will have your blood taken to test for ____ and _____ in # tubes (about X number of teaspoons) of blood will be taken from a vein in your arm. The needle stick may produce some discomfort and possibly some soreness and discoloration of the skin due to blood leaking from the vein; this discoloration may last a few days but it is generally harmless. Infrequently, drawing blood causes someone to faint. This blood draw procedure should take only a few minutes. C. You will do breathing tests to assess your lung function. You will be asked to breathe in as deeply as you can and forcefully blow out as quickly and completely as possible through a tube that you place in your mouth. You will be asked to do this at least (three) times, and possibly more times. This test may be tiring, and you may feel momentary lightheadedness or chest discomfort. If, at any time, you feel unable to continue, the test will be stopped. The test typically takes five to ten minutes. D. You will do urine tests for _____ and _____. You will be asked to urinate, in private, into a container that a NIOSH representative will give you. The only time involved is that required to produce the urine specimen and return it to the technician.

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4	**What other tests will my blood, urine, or ___ be tested for?**	*Your (blood, urine, other biological material) will be used only for the tests specified above. The specimen(s) will be identified only by an arbitrary number, which can be linked to you only by the HHE medical investigators, not the laboratory. The specimens will be retained for six months after the health hazard evaluation final report is issued in order to re-test the specimens in case a question about the original analysis arises.** ** [If pertinent] In addition, NIOSH would like your permission to store your remaining (blood, urine, other biological material) for future research purposes not related to the current health hazard evaluation. In this case, we would remove any personally identifying information from the stored specimens so that they can no longer be linked to you. There is no direct benefit to you for allowing us to use these specimens for research purposes other than making a contribution to science. You may participate in the health hazard evaluation even if you choose not to allow us to store your specimens anonymously.*
5	**Are there any risks?**	A. One risk, besides the slight discomfort and inconvenience from the medical tests as previously described, is that a test result may be outside the range of "normal" even though nothing is wrong. This could result in a recommendation for further medical evaluation that, ultimately, may not have been necessary. B. The test(s) on your (blood, urine, other biological material) are experimental. Guidelines do not exist regarding the(se) test(s) or their breakdown products or how to interpret the levels. The tests may not measure all the drugs you are exposed to at work, and the results may not be interpretable. Although we will be using the most up-to-date medical information available, we may not be able to tell you what the tests mean in terms of your health. We will not share the results of your _____ tests or your questionnaire responses with anyone, but your results will be combined with others and reported as a group. There is a risk of loss of confidentiality regarding participation, questionnaire responses, and _____ analysis results. To minimize the risk of loss of confidentiality, we will use identification numbers and not put your name on the urine specimens or the questionnaires. Results will be kept in locked, secured filing cabinets in the project officers' offices. If you have any comments about the tests/procedures, you should contact (name, title, and phone of Medical Officer).
6	**Is my participation voluntary?**	The NIOSH Health Hazard Evaluation is voluntary. You may choose to be in the Health Hazard Evaluation or not. You may choose to answer any or all questions. You may drop out any time for any reason without consequences to you. *You can inform participants of the importance of full participation or that it is necessary if they are to be included in the HHE results. NIOSH employees should be informed of IRB policy on being a participant (NIOSH employees)* http://inside.niosh.cdc.gov/hsrb/Checklists.html

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7	**What if I'm injured or harmed?**	On-site emergency treatment will be provided. 911 will be called if needed. Medical care or compensation will not be provided. If you are injured through negligence of a NIOSH employee you may be able to obtain reimbursement under Federal Law. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor.
8	**Will I be reimbursed or paid?**	You will not be paid or reimbursed for participating in the Health Hazard Evaluation.
9	**Are there other benefits?**	*List results of clinically relevant medical procedures or diagnostic tests, and other useful information provided to the participant and their physician with permission. If there are no personal benefits, state so. Workplace or societal benefits can be noted secondarily*. Your participation may benefit you, your coworkers, and possibly other people, as a result of what is learned from this health hazard evaluation. Other benefits to you from participating in this evaluation include receiving the information from the results of the free medical tests described under number 3 above.
10	**Will my personal information be kept private?**	*Recommended language*: NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. There are conditions under the Privacy Act where your information may be released to collaborators or contractors, health departments or disease registries, to the Departments of Justice or Labor, or to Congressional offices. *If applicable, note Assurance (308d) or Certificate (301d) of Confidentiality. You can add that personal identifiable information will be destroyed at some specified time. Or:* The study is anonymous. We will not be collecting or recording any personal identifiable information.
11	**Will I or anyone else receive study results?**	*We will send you a letter with your individual results of the _____ sampling and the (blood, urine or biological material) tests. We will send your employer and an employee representative a letter with summary results. Your individual results will not be shared. Upon completion, we will send a final report to your employer and employee representative. The report will be posted on the NIOSH web site.* *NIOSH will provide you and your doctor (if you wish) with all findings from your medical tests (and any other examinations). We will do this when the health hazard report is finished, or sooner, if appropriate. The overall health hazard report results (without names or other personal identifying information) will be provided to the company and union (or other employee representative); the company is required to post a copy of the final report in a place accessible to employees for a period of 30 days. In addition, if you so request, NIOSH will send you a copy of the final report.*

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12	**Who can I talk to if I have more questions?**	For questions about the research study, contact the principal investigator, *name* at *e-mail address* or *telephone number.* For questions about your rights, your privacy, or harm to you, contact the Director of Human Research Protections, Mark Toraason at *mtoraason@cdc.gov*, or 513-533-8591.
13	**Your signature**	The study was explained to me. My questions were answered. I agree to be in the study. _____ Printed name of participant [*Optional*] _____ Participant signature Date I have accurately described this study to the participant. [*Optional*] _____ NIOSH representative signature Date
14	**Additional consent**	*Additional signature lines or to-be-checked boxes can be included to provide an opportunity to opt in or out of ancillary elements of the protocol such as the use of photographs, requesting that medical results be sent to a personal physician, or allowing data or biological samples to be used in future research.*