OMB # _____
Expiration Date: _____

National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
U.S. Public Health Service
U.S. Department Of Health and Human Services

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION FOR RELEASE OF INFORMATION

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You are being asked to participate in a CDC/NIOSH research study. This form describes your participation, your rights as a participant, and how NIOSH will treat your records.

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TITLE: **Long-Term Efficacy of a Program to Prevent Beryllium Disease**

PROJECT OFFICER: Christine Schuler, Ph.D. (800) 447-8305
CDC/NIOSH, 1095 Willowdale Road, Morgantown, WV 26505

BACKGROUND:

Some people who are exposed to beryllium develop *beryllium sensitization*, which is similar to an allergy. Beryllium sensitization is detected in the laboratory by exposing white blood cells to beryllium in a test tube. This test is called the *beryllium lymphocyte proliferation test*. An abnormal test is a sign of sensitization only. Beryllium-sensitized people may have beryllium disease in their lungs. Additional tests at a medical center are needed to establish whether a sensitized person has *chronic beryllium disease*. We know some beryllium-sensitized persons will develop chronic beryllium disease over time.

There are currently no preventive programs that have been demonstrated to have long-term effectiveness in preventing beryllium sensitization and chronic beryllium disease among beryllium-exposed workers. In 2000-01 Brush Wellman Inc. introduced changes to enhance their existing preventive program. Early evidence suggests that this enhanced preventive program has reduced the incidence of beryllium sensitization, as defined by the occurrence of confirmed abnormal beryllium lymphocyte proliferation tests, among newly hired workers never before exposed to beryllium. However, the follow-up has so far been limited to current workers, the duration has been too short to show a reduction in chronic beryllium disease, and it is possible that sensitization has been delayed, rather than prevented. This study will determine whether additional workers have become sensitized and, if so, to investigate what may have contributed to the development of sensitization.

In addition, some people may be more susceptible to sensitization and chronic beryllium disease because of certain forms of genes they inherit from their parents. NIOSH is also studying the genes that might be involved in beryllium sensitization and chronic beryllium disease, and how genes and exposure to beryllium affect risk of disease.

DESCRIPTION:

We are asking all current and former Brush Wellman Inc. workers, who were hired after the enhanced comprehensive preventive program was implemented at Tucson, Elmore and Reading, to be part of this study. What we learn may help to prevent disease by evaluating whether the preventive program has significantly reduced the development of sensitization among workers hired at each of these facilities after the program began.

Your participation will include: completing a consent form; giving a blood sample; completing a medical and work history questionnaire; and giving written permission to review your records. 1) *Blood sample*. We will draw about *three tablespoons* of your blood. Most of this blood will be used for the beryllium lymphocyte proliferation test to see if you are sensitized to beryllium. With your permission, the rest of your blood will be sent to NIOSH for genetic research studies. Because genetic research is developing very quickly, we also ask your permission to store any extra sample from this last tube for possible future genetic research on beryllium disease. This research might involve laboratory tests that have not yet been developed. In some cases, your extra sample might be used to help laboratory scientists develop new tests. If you give permission, any extra sample will be stored with a unique number so that we know it is yours and can link it with your other information. We will store this extra sample for as long as NIOSH conducts beryllium research. You can take part in the testing for beryllium sensitization without taking part in the genetic analyses.2) *Medical and Work History Questionnaire*. The questions are about your work with beryllium, lung or chest symptoms, and your smoking habits. 3) *Record Review*. We ask your written permission to review some of your records, including

your medical records about chest and skin conditions, beryllium sensitization, and chronic beryllium disease; your Brush Wellman Inc. personnel records about where you may have worked and the kind of work you did; and any previous beryllium research records.

It should take about *30 to 60 minutes* to read and complete this consent form, wait for your blood to be drawn, and complete the questionnaire. No alternate procedures exist for conducting this research.

NOTIFICATION OF RESULTS:

1) Beryllium lymphocyte proliferation test. NIOSH staff will send you the results of your beryllium lymphocyte proliferation tests about a month after your blood is drawn. If you request, NIOSH will send these results to your doctor. If your results are abnormal, we will recommend that you seek medical evaluation to see if you have any lung effects related to beryllium. NIOSH will not pay for this additional evaluation or for any treatment if you have chronic beryllium disease. However, the Energy Employees Occupational Illness Compensation Program, funded by the U.S. Department of Energy and administered by the Department of Labor, pays for medical evaluation of sensitized former and current employees, and provides a monetary benefit for those with chronic beryllium disease. If you have abnormal blood tests or have chronic beryllium disease, you will need to contact the Department of Labor to apply for these benefits.

If you have abnormal test results, you may also choose to discuss your results with Brush Wellman Inc. NIOSH will not share your beryllium lymphocyte proliferation test results with Brush Wellman Inc. unless you permit us to do so.

2) Genetics result. At this time, it is not possible to tell a beryllium worker if he or she will get chronic beryllium disease because of his or her genes. The genetic analyses that we will be doing are not used by doctors to diagnose disease or for public health screening. We will not automatically send you your personal *HLA-DP*^{Glu69}genetic result. If you agree to participate in the genetic portion of the research, you can request your personal *HLA-DP*^{Glu69} gene information at any time. We will not send your genetic results to anyone else, even with your permission.

3) Research results. We will send you a report of the overall results of our research, including the genetic research. We will let you know if genetic analyses may help predict what will happen over time to people who are sensitized to beryllium or who have chronic beryllium disease, so that you can weigh the risks and benefits of seeking your own genetic results.

RISKS AND BENEFITS:

The only *physical risk* involved in this study is in giving the blood sample, which is a standard medical procedure. Blood will be drawn from a vein in your arm by a trained professional. This may cause some pain

from the needle stick, bruising where the blood is drawn, and occasionally, dizziness or fainting. If you have any reaction to this procedure you should let the person who drew your blood know, and contact Dr. Schuler at (800) 447-8305.

Another *possible risk* is in having your personal genetic results. If you have your personal genetic information, some insurance companies or employers may ask you for it. Some insurance companies have stated that genetic results are pre-existing conditions, which you must disclose when you apply for a policy. We do not know of any cases where the specific genetic analyses we are doing have been used to refuse insurance or limit benefits. To protect your results, we have obtained a U.S. Public Health Service *assurance of confidentiality*, which prevents NIOSH from having to release your personal genetic information to insurance companies, employers, and for court subpoenas. However, if you obtain your personal genetic information, NIOSH can no longer protect that information. That is why we do not automatically send you your personal genetic information. If you do not receive your genetic results, you are not at risk of possible insurance/employment discrimination. If our study shows that certain forms of genes are related to sensitization, chronic beryllium disease, or progression from sensitization to disease, this research may help make genetic analyses more common. If, as a result of this research, we recommend future testing of people who are considering if they want to work in the beryllium industry, persons with some forms of genes could suffer economic consequences. There are several laws, in effect or under consideration, that may help to prevent discrimination.

A *benefit* to taking part in this study is finding out if you have become sensitized to beryllium since your last beryllium lymphocyte proliferation test. If you are sensitized to beryllium, you may have a much greater chance of having or developing chronic beryllium disease than a person who is not sensitized to beryllium. This information will allow you to seek appropriate medical diagnosis, regular medical checkups, and the earliest possible treatment. If you have abnormal blood tests, you may be eligible for medical benefits from the Energy Employees Occupational Illness Compensation Program; if you are subsequently diagnosed with chronic beryllium disease you may be eligible for both medical and monetary benefits.

If you already know you are sensitized to beryllium or have chronic beryllium disease, a *benefit* to taking part in this study is that you will contribute to our understanding of how some beryllium-exposed people develop beryllium sensitization and chronic beryllium disease, and what happens to them over time. This information may lead to preventive actions that can be taken by individuals and employers.

You will not have to pay anything to participate in this study, nor will you receive any payment.

USE OF INFORMATION AND CONFIDENTIALITY:

NIOSH is a government research organization within CDC, which is part of the Department of Health and Human Services. We can collect your questionnaire and medical information, including your social security

number, because of laws about public health and occupational health (Public Health Service Act, Section 301 [42 U.S.C. 241], the Occupational Safety and Health Act, Section 20 [29 U.S.C. 669], and the Federal Mine Safety and Health Act of 1977, Section 501 [30 U.S.C. 951]). The information you supply is voluntary. There is no penalty for not providing it. The information will be used to study conditions related to occupation, to determine their causes, and to prevent them in the future. Your medical history, work history, and lymphocyte proliferation information will be kept confidential to the extent legally possible as part of the CDC Privacy Act system (09-20-0154, "Medical and Laboratory Studies"). You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. The conditions under which we might release this information are listed in Appendix A (the Privacy Act). NIOSH will send you a list of who has obtained your records if you request it. Any report or publication of this research will not contain information that could identify you as a participant in this study.

Personally identifiable genetic information obtained by NIOSH or its contractors as part of this research is collected and maintained at CDC under Section 306 of the Public Health Service Act (42 USC 242k). An *assurance of confidentiality,* granted under Section 308(d) of the Public Health Service Act (42 USC 242 m(d)), was obtained for this research to give the results from genetic analyses the highest possible level of protection. This assurance of confidentiality protects personally identifiable genetic research results held by NIOSH from court subpoena or order or any undescribed uses of the data, for example, requests from insurance companies or employers. NIOSH and its contractors will not release your identifiable genetic information to anyone except you. *Brush Wellman Inc. will not have access to your genetic information.* The assurance of confidentiality applies to past, current, and future genetic research results generated or received as part of this study. Any report or publication of this genetic research will not contain information that could identify you as a participant in this study.

RIGHT TO WITHDRAW:

Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

COMPENSATION FOR ILLNESS OR INJURY:

Physical injury from this research is unlikely, and medical care is not provided, apart from emergency response on the part of the person who draws your blood. If you are injured through the negligence of a NIOSH employee, you may be able to obtain compensation under Federal law. If you want to file a claim against the Federal government, you should contact the Public Health Service Claims Office at (301) 443-1904. If you are injured through the negligence of a contractor hired by NIOSH, your claim would be against the contractor, not the Federal government. If an injury should occur to you as the result of your participation, you should contact Dr. Christine Schuler at NIOSH, Division of Respiratory Disease Studies, 1095 Willowdale Road,

Morgantown, WV 26505. Her phone number is (800) 447-8305. Or you may contact Dr. Michael Colligan at NIOSH, Education and Information Division, 4676 Columbia Parkway C-11, Cincinnati, OH 45226. His phone number is (513) 533-8222.

VOLUNTARY CONSENT:
I have read this consent form, understand what it says and received a copy of the conditions for data release under the Privacy Act (Appendix A). Any questions I have about this research have been answered by Dr. Schuler or her representatives. My signature below means that I freely agree to participate in this research study by:

1. Completing a questionnaire interview: Yes___ No___

2. Providing a blood sample for the beryllium lymphocyte proliferation test: Yes___ No___

3. Giving permission for NIOSH to provide Brush Wellman Inc. with my beryllium lymphocyte proliferation test results: Yes___ No___

4. Having genetic analyses performed on a sample of my blood: Yes___ No___

5. Giving permission for any extra sample to be used in future beryllium-related genetics research: Yes___ No___

Participant signature _____ Date _____

Printed name _____ _____ Plant _____

Social Security Number _____ Date of birth _____

I, the NIOSH representative, have accurately described this study to the participant.

Representative signature _____ Date _____

1 copy to participant
1 copy to NIOSH

REQUEST AND AUTHORIZATION FOR RELEASE OF INFORMATION

I request and permit the project officer to inform the following physicians or health care facilities, whose names and addresses I have entered below, of any results from my beryllium lymphocyte proliferation test.

(**Do not leave blank**. Write "NO" where you do not wish to give a name and address.)

1. My personal physician(s):

Dr. _____

Street _____

City _____ State _____ Zip _____

Telephone _____

2. Other physician or health care facility:

Dr. _____

Street _____

City _____ State _____ Zip _____

Telephone _____

Participant signature _____ Date _____

Printed name _____ Plant _____

Social Security Number _____ Date of birth _____

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REQUEST AND AUTHORIZATION FOR RELEASE OF INFORMATION

I hereby give permission to the National Institute for Occupational Safety and Health (NIOSH) to review and obtain a copy of any records concerning me from my previous participation in research on beryllium sensitization screening, chronic beryllium disease, and/or genetic analyses. These records include any questionnaire, beryllium blood lymphocyte proliferation tests, beryllium exposure estimates, medical records, and/or genetic analyses obtained by Brush Wellman Inc. A photocopy of this form is acceptable in place of the original.

Participant signature _____ Date _____

Printed name _____ Plant _____

Social Security Number _____ Date of birth _____

Appendix A

The information you provide will become part of the CDC Privacy Act System, 09-20-0154, "Medical and Laboratory Studies" and may be disclosed to

- Private contractors assisting NIOSH;
- Collaborating researchers under certain circumstances to conduct further investigations;
- One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;
- Congressional offices assisting an individual in locating his or her records;
- The Department of Justice in the event of litigation.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.