This form is provided in the Registrant packets and is completed by the Registrant when wishing to be considered for participation in the program or renewing their five-year agreement. The Registrant is requested to sign, date, have witnessed and return this form to be considered or maintain active registration.

United States Transuranium and Uranium Registries
Registries Information and Research Study Consent Form

Study Title: US Transuranium and Uranium Registry

Researcher: Dr. Sergei Tolmachev
Director of United States Transuranium and Uranium Registries
Washington State University, College of Pharmacy
1845 Terminal Drive, Suite 201, Richland, WA 99354
Phone: (509) 946-6870 or (800) 375-9317
Fax: (509) 946-7972

You are being asked to take part in a research study. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you don't understand. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is this study about?

The purpose of the United States Transuranium and Uranium Registries is to improve understanding of the uptake, distribution, retention, dosimetry, and bio-molecular effects of the uranium series elements and the transuranic elements, such as plutonium and americium, in humans. (These heavy elements are often referred to by the chemical classification term: ACTINIDE.) The results of this effort provide basic scientific information for verification or refinement of current radiation protection standards for workers. Data are obtained from health physics records, medical files, questionnaires, and the radiochemical analyses of tissue from individuals with known exposure to one or more of these elements. Radiation doses to body organs are calculated and combined with information about effects that might have been caused by the radiation to produce dose/response relationships. In some special cases pathological and/or bio-molecular changes caused by materials commonly associated with Pu exposure, e.g. beryllium, may also be studied. Information from individual cases is combined with that of other registrants to construct general mathematical models, which can be used to assess radiation protection standards.

What will I be asked to do if I am in this study?

There are four ways in which you, a current or former employee in the nuclear industry, can help the scientific community extend its knowledge of how the actinide elements are taken up, deposited and retained in the human body:

1. **Records Release:** By authorizing the release of your health physics and medical information to the Registries, copies of these records will become available for Registry interpretation.
2. **Special Studies:** Certain registrants may be asked to participate in special studies that might involve procedures such as collection of excreta and/or blood sample(s), in-vivo (whole body) counting, or periodic physical examinations by qualified medical and health physics personnel. For each special study, an informed consent document will be prepared for the participant's signature, which will include a full description of the special study, any risks involved, and the benefits expected.
3. **Routine Autopsy/Surgical Specimens:** By authorizing a postmortem examination, the Registries will receive and analyze selected organs and tissues for the presence of actinide elements and pathological or possibly bio-molecular changes in these specimens. If the participant has surgery in which tissue is removed, the Registries are interested in radiochemical analysis of the tissue for the presence of actinide elements. Such surgery, especially applies to tooth extractions and removal of portions of bone.
4. **Whole Body Donation:** Just as you may donate your entire body to a medical school for research purposes, you may authorize a whole body donation to the Registries. Priority for accepting the donation of a whole body is extended to those individuals with a substantial documented deposition and/or exposure history.

Are there any benefits to me if I am in this study?

There is no direct benefit for participating in this study except for the knowledge that your donation will make a significant contribution to radiation protection of nuclear workers.

Are there any risks to me if I am in this study? Will my information be kept private?

The only potential risk to you from participating in this program is the possible loss of confidentiality or personal information. The Registries take every possible precaution to protect the registrant and specifically prohibit identification of registrants by name or the use of personal identifiers (e.g. addresses or social security numbers) at the time that Registries data are summarized, presented in public forums, or published in the scientific literature. Rare exceptions to this policy require the written and signed permission of the registrant or next of kin for the disclosure of such information.

Are there any costs or payments for being in this study?

There will be no costs to you for taking part in this study. The Registries pay the expenses incurred in obtaining an autopsy by an independent private pathologist and in performing the radiochemical tissue analysis; in addition, the Registries provide the spouse or next of kin $500 as a memorial for participating in the program. All information obtained from the donated postmortem tissue is available to the registrant's spouse or next of kin upon written request to the Registries.

Will my information be kept private?

The Registries make every effort to ensure that the personal privacy of each registrant and the next of kin is protected. This policy specifically prohibits identification of registrants by name or the use of personal identifiers (e.g. addresses or social security numbers) at the time that Registry data are summarized, presented in public forums, or published in the scientific literature. Rare exceptions to this policy require the written and signed permission of the registrant or next of kin for the disclosure of such information.

Your participation in the Registries is strictly voluntary and you may withdraw from the program without cause at any time you desire. Registry agreements must be renewed with a newly signed and witnessed authorization every five years. This provides the registrant with an additional opportunity to terminate the agreement.

If you wish at this time to become a registrant, please complete this informed consent document as indicated below and mail it to the Registries. After acceptance by the Registries, you will be sent a signed and witnessed copy of this information and informed consent form for your records.

Who can I talk to if I have questions?

If you have questions about this study or the information in this form, please write or call the researcher /professional staff at the address provided on the top page of this consent form.

If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Central Department of Energy Institutional Review Board (CDOEIRB) at 865-574-4359 or CDOEIRB@orau.org.

What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I have read and understand the terms and conditions of the described research programs and I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

_____ _____

Signature of Donor Date

_____
Printed Name of Donor

_____ _____
Signature of Witness Date

_____
Printed Name of Witness