

Kingston Project Facts

Information Sheet and Informed Consent Form

What is the purpose of the Kingston Project Screening Program (KPSP)?

The purpose of this screening program is to provide medical screenings to individuals potentially affected by the Kingston coal ash spill that occurred on December 22, 2008. The screening will help determine whether or not people have developed any adverse health effects as a result of the spill.

Participation in this screening program is completely voluntary. You may choose not to be in the program, or if you choose to be in the program you may withdraw from the program at any time. You are not giving up any legal rights by participating in the medical screening. Your consent is indicated using the Informed Consent Form at the end of this Information Sheet.

What can I expect from the medical screening?

As a person who lives or lived close to the spill, you will be offered specific medical examinations based on the substances that have been measured in the coal ash. You will also be asked to complete a questionnaire that asks about medical symptoms that you may have experienced since the spill and other health questions that will help the doctors interpret your medical test results.

If you are found to have adverse health effects possibly related to exposure to coal ash, you will be referred to your private physician for follow-up care and to the Tennessee Valley Authority (TVA) to determine your benefit status for further medical evaluation.

Who is funding this program?

The TVA is funding this program. Oak Ridge Associated Universities (ORAU) in Oak Ridge, Tennessee, is managing the program with its program partner Vanderbilt University Medical Center (VUMC), in Nashville, Tennessee.

Who can receive a medical examination through the Kingston Project?

The KPSP can provide medical examinations to any citizen living within two miles of the Kingston ash spill, and to those living farther away who believe that their health has been adversely affected by the spill.

Do I have to have the medical examination or do I have to have all of the tests performed that are offered in the screening program?

No. Your participation in this medical screening program is strictly voluntary. You may refuse any of the tests offered to you. Talking with your family, your doctor, or other people you trust may help you decide. The screening program medical professionals and staff can also help answer any questions that you might have and may be contacted at (865) 576-3115.

What will happen if I decide to have the KPSP medical examination?

You will be scheduled by the KPSP team to have a medical examination and associated tests at Covenant Health facilities in Roane County. A typical medical examination may include the following:

- Review of your questionnaire information
- Breathing test (spirometry)
- Chest x-ray
- Blood draw (approximately 4 tsp. for adults and 1 tsp. for children)
- Urine specimen collection
- Physical examination by a medical toxicologist
- Height, weight, and vital measurements

A blood specimen will be taken from a peripheral vein, usually in your arm. There is little physical risk in the blood draw procedure. In a few people slight pain and a small area of bruising may occur at the site of the blood draw. The bruising usually subsides in 3-5 days.

When will I receive the results of my KPSP medical examination?

You will receive a letter from the program physicians informing you of your complete medical screening results within 4 to 6 weeks.

What happens if a medical abnormality is found during the medical examination or in my blood work?

The program physician will provide the results of your medical screening to you with a recommendation that you provide all information to your personal physician for inclusion in your medical file and for any appropriate follow-up care. The medical screening program will NOT contact your physician directly except in an emergency or at your request. However, if at any time one or more of your test results deserve “urgent” notification, you will be contacted so that you can obtain the appropriate treatment. You should be aware that—as with most tests—the medical tests performed during the examination can yield results that are inconclusive, and the doctors will decide if any tests need to be repeated. It is important that you share the results of the program examination with your personal physician as part of your continued health care.

What are the costs and benefits to me if I participate in the program?

There is no financial cost to you for the medical screening. You may or may not elect to follow any recommendation or referral made by the program physicians. This program will not pay for any follow-up medical care. If ORAU determines that you have some adverse health effects and if those adverse health effects likely have resulted from the Kingston coal ash spill, TVA has stated that they will assume responsibility for medical expenses you incur from undergoing recognized and accepted medical treatment for those adverse health effects.

It is possible that health issues not associated with coal ash or its constituents may be discovered during the process of this medical screening. If a non-related health problem is discovered and you decide to seek medical treatment, you will be responsible for those costs.

The principal benefits to you are the results of the medical examination. You also have the opportunity to contribute to our understanding of health as it may relate to unintentional exposures to fly ash.

What will happen to the records of the medical examination results?

Your test results will be treated as confidential medical records or Protected Health Information (PHI) and will only be disclosed consistent with laws and legal precedents governing confidential medical records or as required by a court order.

The results of tests and examinations may be published in technical reports or presented at scientific meetings, but will not identify any individuals. The results of your medical examination and other screening tests will be made available to you and, upon your request, to your personal physician.

Identifiable information about you and your test results will be placed in a secure database that will be used by the screening team to notify you of results and keep track of where you are in the medical screening process.

The results of your medical examination will only be available to the people listed below. Some of these people may require access to records that identify you by name:

1. The ORAU KPSP staff who will review your results and maintain a file of your records
2. Physicians from VUMC who will maintain the permanent file of your records, who will review your results, and will explain whether further testing is necessary for you
3. The Oak Ridge Site-Wide Institutional Review Board (ORSIRB) who is responsible for reviewing and approving all materials related to this screening
4. Others as required by applicable law or as required by court order

What laws protect my privacy if I consent to participate in the KPSP?

State medical and nursing licensing boards enforce codes of ethics that require doctors and nurses to keep medical information confidential. Medical personnel will adhere to the strict guidelines that apply to PHI as explained by the Privacy Rule in the Health Insurance Portability and Accountability Act (HIPAA). In addition, ORAU protects all records in accordance with relevant Federal laws. The consent form you sign also provides additional protection.

Can privacy and confidentiality of my medical records be guaranteed?

No. Access to or release of records could be required under court order, but it is unlikely. Personal identifiers will not be published in any reports.

**KINGSTON PROJECT SCREENING PROGRAM (KPSP)
INFORMED CONSENT STATEMENT**

Program Manager: Donna L. Cragle, Ph.D.
Occupational Exposure and Worker Health
Oak Ridge Associated Universities
P.O. Box 117, Oak Ridge, TN 37831-0117
Telephone (865) 576-2866

Funding Agency: Tennessee Valley Authority

PARTICIPANT'S AUTHORIZATION

I have read: (Please initial items to indicate that you have read them.)

_____ the attached information about the KPSP. I have or will contact the KPSP at (865) 576-3115 to discuss any questions that I may have prior to or after my scheduled appointment. I am aware that I am free to withdraw at any time from the program for which I am volunteering. I understand that I will receive the results of any medical tests from the KPSP physicians who are directing and reviewing the medical examination.

_____ that medical follow up is not provided by this screening. If ORAU determines that I have some adverse health effects that may have resulted from the Kingston coal ash spill, TVA has stated that they will assume responsibility for medical expenses I incur from undergoing recognized and accepted medical treatment. I may or may not pursue any recommendations or referrals made by the KPSP physicians.

_____ that the results of any tests, examinations, or analysis of this medical screening program may be published or presented at meetings, but that I will not be identified personally.

_____ that the records of my participation in this program and the results of any tests or examinations that I consent to are confidential medical records that may only be disclosed consistent with laws and legal precedents governing confidential medical records or as required by a court order.

_____ that if I have additional questions about this program or my participation in it, I can contact Dr. Donna Cragle, ORAU, at (865) 576-2866; Dr. Donna Seger, VUMC, at

(615) 936-0760; or the Chair of the Oak Ridge Site-Wide Institutional Review Board at (865) 576-1725.

_____ that I will be given a copy of this Informed Consent Form.

CONSENT STATEMENT

The purpose of the KPSP, procedures to be followed, risks, and benefits have been explained to me. **I have read that any questions I may have concerning any part of the physical examination and or medical results should be directed to the KPSP at (865) 576-3115.** I have read this consent form and agree to be in this program with the understanding that I may withdraw at any time. I will be given a signed copy of this consent form with the results from my examination.

For parents: I have read this consent form and agree to allow my child to be in this screening with the understanding that I may withdraw him/her at any time. If my child is 6 years of age or older, this screening has been explained to him/her and he/she agrees to participate.

_____ Participant Name

_____ SSN

_____ Participant Signature or Child's Assent Signature

_____ Date

_____ Parent's Signature

Consent form approved by the Oak Ridge Site-Wide Institutional Review Board (FWA00005031) and effective August XX, 2009, for a period of up to 12 months ending on August XX, 2010. The approval letter is on file at the ORAU KPSP office.

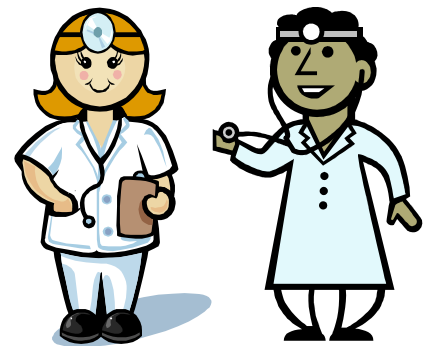
Some ash spilled into the river in December of last year. You are here today to have some tests to make sure you are healthy.

Kingston Project Surveillance Program

First, whoever takes care of you is going to ask you questions about how you are feeling.



Then, you are going to have some tests. Very nice people are going to take a picture of your chest and get about a teaspoon of blood from you. They will check your breathing, too.



In a couple weeks, you will go to see a doctor. He will ask you more questions about how you feel and then check you.



Finally, everyone who cares about you will know if you are feeling okay.

