## Description of the Fernald Medical Monitoring Program University of Cincinnati College of Medicine

Former Medical Director:	Robert Wones, MD Department of Internal Medicine	
Research Director:	Susan Pinney, PhD Department of Environmental Health	
Program Coordinator:	Jeanette Buckholz, RNC, MSN, CEN Department of Internal Medicine	

The Fernald Medical Monitoring Program (FMMP) was a voluntary ongoing medical surveillance program for community residents living within five miles from the perimeter of a former US Department of Energy uranium-processing site. Beginning in 1990, 9782 persons enrolled in the Fernald Medical Monitoring Program (FMMP); of these 8770 were adults (18 years or older) at the time of their first examination. Most participants enrolled during a three-year period from September 21, 1990 to November 30, 1993. Samples of whole blood, serum, plasma and urine were obtained from all participants at the time of the initial examination, and over 160,000 1 ml aliquots of these biospecimens have been stored at minus 80 degrees C since then. Funding for medical examinations expired at the end of 2008.

## Fernald Medical Monitoring Program (FMMP)

Upon entry to the FMMP all participants received a thorough medical examination and diagnostic tests including chest x-ray, electrocardiogram, and pulmonary spirometry. Mammograms and pelvic examinations with collection of cervical pap smears were performed on female participants. Examinations were conducted by Board-certified physicians at clinical facilities in the Medical Arts Building adjacent to the Mercy Fairfield Hospital, the hospital serving most of the community. Mammograms and chest x-rays were obtained at the Mercy Fairfield Hospital, but read by University of Cincinnati faculty members Board-certified in Radiology. Laboratory tests included the usual series for hematology, chemistry and lipid profile of blood serum, and urinalysis. The laboratory analyses were originally done by the University of Cincinnati College of Medicine Department of Laboratory Medicine and later by the Cincinnati Children's Hospital Medical Center clinical laboratory. The FMMP administrative office, the location of screening follow-up, data entry and medical record and radiology film storage, was adjacent to the Mercy Fairfield Medical Arts Building. Staff communicated frequently and many traveled from one site to the other during the course of the day.

At conclusion of the examination physicians recorded any new medical diagnoses apparent at the time of the examination, as well as diagnostic uncertainties requiring further diagnostic testing. Nurses employed by the program conducted participant follow-up by phone for at least six months on all those needing further testing or treatment by their usual primary care practitioner. (We believe that this follow-up was a key to our excellent record of continuing program participation.) New diagnoses recognized through this follow up also were recorded on the medical record. Outside medical records (usually a pathology report) were obtained to validate any new diagnosis of cancer. This same procedure was used at the time of the ensuing periodic medical examinations, offered every three years until 1999. In December 1998, financial analysis of monies left in the Settlement Fund indicated that re-examinations could be offered every 2 years (1999 to 2008). By the end of the program, the FMMP conducted 42,217 medical examinations. Female participants age 40 and older were offered mammograms each year (including years when a complete medical surveillance examination is not scheduled), and men over 50 years are offered a PSA every other year.

Following the initial questionnaire, participants also were asked to complete yearly questionnaires requesting information about new medical problems and recent hospitalizations and surgeries, resulting in 94,771 completed questionnaires from adults. Yearly questionnaire return rates varied by Program year, but in 2007 were 51.6% of the original enrollees. Our yearly questionnaires were computer-generated, so that participants who missed a past questionnaire were re-issued critical data items from those missed questionnaires, greatly improving total ascertainment on any data item. Continued participation in the program at the

time of re-examinations fell 23% at the first re-exam for adults and has remained at about 50% for each examination since that time. (Some participants skipped one exam but then returned for the next one.) Only 216 participants withdrew from the Program and are no longer contacted or followed (except to obtain information when we learn of their death); 184 participants are lost to follow-up.

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## Archived specimens:

At first examination, sufficient biospecimens were collected to biobank three 1-ml aliquots of whole blood, plasma, serum, urine and urine with buffer, or 15 aliquots per person for future analyses. Since then, these specimens have been stored in minus 80 degree freezers. Although one of four freezers (at Holmes Hospital) failed during the July 4 weekend in 1996, and all samples in that freezer were lost, many of the plasma and serum samples were replaced when participants came for their next examination. Few of the over 160,000 biospecimens have been used for research. Since 2001 specimens have been stored in six freezers at CCHM Research Lab (old Bethesda Oak Hospital space). The status and temperature of each freezer is continuously monitored by a central alarm system with



established protocols for notification and transfer of specimens if needed. The freezers have a  $CO_2$  back-up system and undergo scheduled maintenance through a contract with the SoLow Company.

We have a large inventory database of all of the biospecimens, with queries that enable us to retrieve information about biospecimens linked to a specific program participant.