

National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

Date:	July 2, 2013
То:	Office of Management and Budget (OMB)
Through:	Keith Tucker, Report Clearance Officer, HHS Seleda Perryman, Report Clearance Officer, NIH Vivian Horovitch-Kelley, PRA Project Clearance Liaison, NCI
From:	Jane Hoppin, ScD, National Institute of Environmental Health Studies (NIEHS)
Subject:	Revision of "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases among Men and Women in Agriculture" OMB#: 0925-0406, current expiry: 4/30/2016

This is a request for OMB to approve the revision request of "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases among Men and Women in Agriculture." We request that OMB consider a compressed timeline for this submission that was recently reviewed and approved by OMB. This revision requests approval of the dust collection component to the already approved AHS. The goal is to field the dust collection component of the AHS in August, 2013. Timely approval will enable us to incorporate this component into a larger number of home visits, over a broader number of counties in the study area, thereby increasing the representativeness of the sample of cohort members who provide dust specimens. Thank you for your thoughtful consideration of this issue.

The Agricultural Health Study (AHS) is a cohort study of 89,568 licensed private and commercial applicators pesticide applicators and the spouses of the private applicators in Iowa and North Carolina that is to be followed for 25 years or more. The stimulus for this prospective investigation comes from the growing evidence that, despite a low mortality overall, farmers experience an excess of several cancers, including lymphatic and hematopoietic system, connective tissue, skin, brain, prostate, stomach and lips. These excesses have been observed in retrospective epidemiological studies among agricultural workers in several countries, and some (brain, NHL, multiple myeloma, and prostate) are also increasing in the general populations of these countries. This suggests a common set of exposures which may explain the high rates in farmers and rising rates in the general population. The design of the study was developed at the NCI with subsequent collaboration with the National Institute of Environmental Health Sciences (NIEHS), the Environmental Protection Agency (EPA), and the National Institute for Occupational Safety and Health (NIOSH). NCI is primarily interested in cancer outcomes and NIEHS is interested in other disease outcomes. EPA and NIOSH are providing support for a limited exposure assessment effort.

Collecting information for phase IV follow-up interview (2013-2015) as well as the ongoing Study of Biomarkers of Exposures Effects in Agriculture (BEEA) and buccal cell collections continues. The primary objective of the AHS study remains to be determination of the health effects resulting from occupational and environmental exposures in agriculture. This revision is to initiate and complete a new dust specimen component as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA). The dust component will include a brief paper-and-pen questionnaire mailed to the participant in advance of the home visit. At the home visit, the study phlebotomist will collect the participant's disposable vacuum bag (or empty the dust from vacuums without disposable bags). We are using similar procedures to ones that have been employed on other NCI studies to obtain information about the dust specimen and to collect and ship the dust specimen.