



National Institutes of Health
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To: Office of Management and Budget (OMB)

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Subject: Renewal 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: 11/2008

This is a request for a renewal of a currently approved collection entitled "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases among Men and Women in Agriculture" for an additional three years. The Agricultural Health Study (AHS) is a cohort study of 89,568 licensed pesticide applicators (both private and commercial applicators) and the spouses of the private applicators in Iowa and North Carolina that is to be followed for 20 years or more. The data collection from respondents and their burden that was approved for the current study has not been completed, and we are requesting an extension to complete the follow-up period of Phase III. The project schedule was delayed due to a delay in funding reaching the field stations which resulted in a late start for data collection. That combined with an unpredicted, slower than anticipated data collection activities has slowed this part of the study.

The stimulus for this prospective investigation comes from the growing evidence that, despite a low mortality overall, farmers experience an excess of several cancers. These excesses have been observed in retrospective epidemiological studies among agricultural workers in several countries. Excess cancers are observed for the lymphatic and hematopoietic system, connective tissue, skin, brain, prostate, stomach and lips. Several of these tumors (brain, NHL, multiple myeloma, and prostate) are also increasing in the general population in many 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.

Farmers, their families, and other pest control workers may have contact with a variety of potentially hazardous substances including pesticides, solvents, fuels and oils, engine exhaust, dust and zoonotic viruses and other microbes. The health effects of pesticide use are the primary focus of the study. The influence of other farm exposures is also being evaluated. A small subset of respondents, who are also being interviewed, will have buccal cell sampling to confirm findings that those individuals with both a family history of prostate cancer and exposure to specific pesticides are at a greater risk of developing prostate cancer. Since the toxicology literature has defined the metabolic pathways of a number of pesticides, the AHS is now ready to study these pathways in relationship with various diseases in molecular epidemiological studies.

The focus of the phase III follow-up period (2005-2008), which will now extends through 2009, is to complete the exposure information and health histories by means of a Computer Assisted Telephone Interview (CATI) for a total of 20,583 subjects from the 74,320 that were initially enrolled, and to follow the cohort to determine disease incidence and mortality.