



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

Through: Mikia Currie, Project Clearance Officer, OPERA, NIH ____
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From: Michael C.R. Alavanja, Dr. P.H.
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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: 10/31/2011

This is to notify OMB that the revision of "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases among Men and Women in Agriculture," has published a 60-Day Federal Register Notice on March 4, 2010. As indicated in the February 25, 2010 email from Julie Wise, OMB, OMB has agreed to waive the 30-Day Federal Register Notice requirement and NCI will share a draft of the revised package with OMB prior to it being formally submitted to ROCIS. This will avoid further delays in approval. OMB should expect to receive this submission formally for review in May, 2010.

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 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.

This revision is to continue and complete the phase III follow-up period (2005-2011). The primary objective of the study continues to be determination of the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Questionnaire data will be collected by using computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents will also be asked to participate in the collection of biospecimens including blood, urine, and buccal cells.