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PI Name:	Chylack, Leo M.D.		
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**Task Description:** 

The NASA Study of Cataract in Astronauts (NASCA) is a cross-sectional and longitudinal five-year epidemiological study of the risk factors associated with cataract incidence and progression in the whole population of American astronauts and two control populations - pilots with military aviation experience and participants in the Longitudinal Study of Astronaut Health (LSAH). The study of risk factors focuses on the types and doses of radiation exposure in space flight, measures of nutrition, and general health. The assessment of cataract will use digital images of the lens and validated measures of severity. The study will measure the prevalence, incidence, and progression rates of cortical, nuclear, posterior subcapsular, and mixed cataracts, and it will relate these measures to measures of radiation, nutrition, and general health. A secondary goal of this project will be to improve the routine annual clinical assessment of the ocular lens by including Nidek EAS 1000 digital imaging of the lens in the annual ocular examination. NASCA contains an initial cross-sectional assessment of prevalence, and a follow-on assessment of progression rates of lens opacification in the populations of astronauts, military pilots, and ground based comparison participants in the Longitudinal Study of Astronaut Health (LSAH). Main goal of cross-sectional study: To determine the prevalence of the three main classes of age-related lens opacification in the complete sample of astronauts and in two control populations: military pilots and ground-based subjects in the LSAH. We will determine the risk of each class of cataract associated with exposure to various components and dosages of radiation during space flight. A secondary goal of the cross-sectional study is to estimate the prevalence of the three main classes of age-related lens opacification and determine the risk of each class of cataract associated with various factors (nutrition, general health, UV radiation, and others) encountered non-space flight. A tertiary goal of the cross-sectional study is to modify the ocular assessment protocol in the astronauts' regular annual medical examination to improve the assessment of the status of the crystalline lens. The main goal of the five-year longitudinal study is to determine the progression rates of the three main types of lens opacification in the complete sample of astronauts, the control populations of pilots and ground-based subjects in the LSAH, and then determine the risk factors associated with cataract progression with a specific focus on the components and doses of radiation exposure during space flight. Specifically, total radiation lens dose, space radiation lens dose, and individual contributions from space galactic cosmic ray and trapped proton lens dose will be assessed. NASA is concerned about identifying and ultimately mitigating the risks to astronaut health of exposure to radiation in space. Several avenues of research now suggest that increased risk of lens opacification may be one of these adverse health effects. In order to address this issue, NASA has approved and funded this five-year, multi-centered research proposal entitled "The Precise Assessment of Prevalence and Progression of Lens Opacities in Astronauts as a Function of Radiation Exposure During Space Flight." The Brigham and Women's Hospital (BWH), the Johnson Space Center (JSC), the Department of Medicine at Baylor College of Medicine (BCM), Wyle Laboratories, and Space Center Eye Associates are the five centers cooperating in the execution of this study. The epidemiologic team at BCM will recruit astronauts and control subjects. Members of the Flight Medicine Clinic at the JSC will perform ocular and general medical examinations and will obtain blood samples for analysis. They will obtain specialized digital images of the crystalline ocular lens that will enable investigators at The Center for Ophthalmic Research at the BWH to derive measures of the severity for each class of cataract. Wyle Laboratories personnel at JSC will create and maintain the main data set of this project, and members of the Radiation Safety Office and the Statistical Branch of the JSC will work with Dr. Chylack, the PI of this project, and the other Co-Investigators to analyze of the data from this project and prepare regular reports and manuscripts. Leo T. Chylack, Jr., M.D. (BWH) originally submitted the proposal as a Supplemental Medical Objective (SMO). The goal of the proposal was to supplement the current annual ocular examination with new measurements that would allow an objective and more quantitative routine assessment of the status of the crystalline lens in astronauts. This supplementary methodology would enable NASA to obtain objective assessments of the clarity of the lens, quantitative, continuous measures of the severity of lens opacification, and, over time, cataract type-specific progression rates. The SMO has undergone review by several intramural boards and a non-advocate peer review (NAR) panel. As a result of this review, the NAR recommended 1) a major expansion of the project to enable measures of the prevalence and progression rates of various forms of lens opacification, and 2) modifications of the number and composition of the control groups to provide comparisons of prevalence and progressions rates of lens opacification in astronauts to those in pilots exposed to the cataractogenic risks of high altitude (but not space) flight and to those in LSAH subjects, who presumably are not exposed to high altitude or space radiation.

## **Rationale for HRP Directed Research:**

Research Impact/Earth Benefits:	Expanding our understanding of the mechanisms of space-radiation-induced cataract may suggest means of reducing the risk of radiation-induced cataract on earth among individuals employed in jobs in which radiation constitutes an occupational hazard. Also, it may suggest improved means of shielding the eyes of patients undergoing radiation therapy. Information about the mechanisms of cataracts in astronauts may suggest additional research into the causes of age-related cataract, the world's leading cause of blindness. Lastly, the longitudinal phase of the study which links nutritional data to the risk of cataract progression may suggest nutritional means of ameliorating the risk of cataract.
	Recruitment: In the NASCA study we are recruiting from three populations: 1) the entire population of living American astronauts, pilots with military flying experience, and members of the Longitudinal Study of Astronaut Health (LSAH). During the last six months of 2004, since recruitment began in July, 2004 we have recruited 51.2 % of our goal. The specifics of our recruiting effort are detailed as follows: Astronauts: 93 males, 21 females, for a total of 114. Military pilots: 60 males, 2 females, for a total of 62. LSAH subjects: 63 males, 11 females, for a total of 74. Grand Total: 250 (51.2%) We have also made additional progress are as follows:
	Human Subjects Committee (HSC) applications: We have completed and secured approval from the HSCs at the Brigham and Women's Hospital, Baylor College of Medicine, and NASA/JSC.
	NASCA Website: At the BWH we have established a secure NASCA-specific server, and we are now uploading administrative information (Manual of Operations, award statements, policies, teleconference minutes, etc.), image data, recruitment statistics, relevant references, and many other study-related materials. The server will also hold a copy of the main NASCA data file prepared by Dr. Wear at Wyle Labs.
	Data Management: Dr. Mary Wear and her staff at Wyle labs are compiling the data sent from the various study sites (ocular and general medical examinations, data from analysis of digitized lens images, radiation exposure statistics, nutritional Food Frequency Questionnaires, demographic data, and routine blood data. The team is about to begin the process of assessing the quality of the data gathered to date. The number of variables will be reduced to those with direct primary relevance to the study's objectives. Lens/Cataract Image Analysis: As of 01/14/05 we have completed the

Task Progress:	analyses of lens images (slif and retroillumination) from 19/ subjects. Also, we have completed the development of protocols for analyzing the different forms of cataract. Statistical Analysis: Dr. Al Feiveson at NASA is currently reviewing the data sets with a goal of developing appropriate statistical models for the initial cross-sectional analyses of the risk factors for cataract prevalence. Radiation Data: A database of radiation doses received by astronauts from all known sources will be used in the NASCA study. The database includes astronaut radiation exposures from medical, aviation training, isotopes, and space radiation. Computer models are used to estimate the lens dose based on available dosimetry for each exposure
	Food Frequency Questionnaire Data: At the time of the 2004 Annual Report, the NASCA team had not selected the format for gathering nutritional data. The indecision was due partly to the uncertainty about the feasibility of using blood to assess the nutritional status of astronauts and controls. We were particularly interested in assessing the antioxidant status of individuals in all groups using anti-oxidant indices. Two factors helped us make the decision against using blood-derived data to assess nutritional status: 1) the cost of these analyses would be prohibitively high even if some of them were done "in house" at NASA, and 2) there were respected peer review publications suggesting that blood levels accurately reflect recent nutritional intake but are not robust as indicators of chronic or long-term nutritional patterns. Having made the decision not to use blood analyses to determine anti-oxidant status, we decided to evaluate nutritional questionnaires as alternative methodologies. The Harvard Food Frequency Questionnaire (HFFQ) proved to be a validated instrument that was reasonably efficient to use in the setting of the NASCA study. Accordingly we obtained HSC approval to use the HFFQ and began using this at the outset of the study. Dale Hardy, our Patient Recruiter is administering these questionnaires in a standardized manner and the Channing Laboratory at the Brigham and Women's Hospital is doing the automated assessment of the nutritional information. Data in electronic form will be sent to Dr. Wear for entry into the NASCA database. Publications: Plans are underway for the first series of publications of the results of the cross-sectional component of the NASCA study. In the spring of 2005 we will have sufficient data to begin these analyses, and we anticipate that we will have the first analytical results in early summer of 2005.
Bibliography Type:	Description: (Last Updated: 08/21/2012)
Presentation	Leo T. Chylack, Jr., M.D. "The NASCA Study – The NASA Study of Cataract in Astronauts" Bioastronautics Workshop in Galveston, TX Jan-2005
Presentation	F.A. Cucinotta, F.K. Manuel, G. Iszard, A. Feiveson, L.E. Peterson, D. Hardy, L.J. Marak, W. Tung, M.L. Wear, and L.T. Chylack, Jr "Historical study of radiation exposures and the incidence of cataracts in astronauts." 9th Biennial Meeting of the International Society of Toxicology (ISOT), Ft. Worth, TX Oct-2004