

APPENDIX C

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., January 3, 1966.

Mr. GREGORY J. AHART,
Assistant Director, General Accounting Office,
Washington, D.C.

DEAR MR. AHART: Enclosed is a statement prepared by the Public Health Service in reply to your draft report to the Congress entitled "Need for Better Planning Before Starting Medical Research Projects." Enclosed also is (1) a chronological history of the Lovelace Foundation grant; (2) a list of reviewers participating in each NIH project site visit and (3) a memorandum for the record dated February 5, 1965.

We appreciate the opportunity of reviewing the draft report.

Sincerely yours,

JAMES F. KELLY, Comptroller.

DRAFT REPORT TO THE CONGRESS OF THE UNITED STATES BY THE GENERAL ACCOUNTING OFFICE ON THE SUBJECT "NEED FOR BETTER PLANNING BEFORE STARTING MEDICAL RESEARCH PROJECTS"

POSITION STATEMENT BY THE PUBLIC HEALTH SERVICE

In this draft report, it is contended that the Public Health Service and the Federal Aviation Agency are both financing long-term medical research projects on the aging of pilots without either party having "(1) determined whether there is a need for two Government agencies to be concurrently sponsoring long-term projects on the aging of pilots, or (2) [taken] steps to consolidate the apparently duplicative research." In GAO's opinion, one long-term research project would have been sufficient to accomplish the research objective of both agencies.

It is recommended that before undertaking research projects, the Secretary "determine whether other Government agencies are engaging in, or are giving consideration to, starting projects in the same areas." If so, "agreements be reached as to which agency should conduct the research and make the results known to the other interested agencies." You recommend also that the Secretary, HEW, and the Administrator, FAA, "determine whether it is in the best interests of the Government for both agencies to continue financing long-term research projects on the aging of pilots, and take appropriate action based on these determinations."

GENERAL COMMENTS

After careful review of the draft report and the records concerning the grant in question, the Public Health Service finds itself in disagreement with all of the major points and conclusions cited in the report. The contents of the report evidence a complete lack of basic understanding of the research mission of NICHD and the ultimate purposes of the PHS-supported study in question as contrasted to the purposes of the Federal Aviation Agency-sponsored study. Further, most of the factual information pertaining to the communication and coordination that took place between the PHS, FAA and grantee staff and the differences between the two studies in question were made known to the GAO staff by NIH Aging Program staff. Although the GAO staff members were given this information, they chose to ignore it in their report. Of greater concern, however, is the GAO recommendation that " * * * before undertaking research projects, the Secretary determine whether other Government agencies are engaging in, or giving consideration to, starting projects in the same areas. * * *". Based on the faulty assumption that one of the many thousands of projects supported by PHS involves research duplicative of that being conducted by another Government agency, the GAO staff implies that controls to prevent

unnecessary duplication of efforts are either non-existent or inadequate. In our opinion, this recommendation by the GAO staff further indicates a lack of understanding of the PHS processes for reviewing research grant proposals and the controls built into such processes which not only serve to avoid unnecessary duplication of effort but also to disseminate research findings to the scientific community.

DIFFERENCES IN PURPOSE

As stated above, PHS disagrees with the report's assertion that both PHS and FAA are conducting or supporting these studies for the same purpose.

The FAA medical research program is an in-house research program conducted for the purpose of meeting specifically defined program needs associated with FAA missions. The Public Health Service extramural medical research program, which is supporting the Lovelace Foundation grant, is a nationwide program of basic medical research conducted by thousands of independent researchers whose projects must survive a highly competitive process of dual scientific review in order to be funded. The purpose of the Public Health Service extramural research program is to increase the store of scientific knowledge bearing on problems of human health.

Thus, there is a basic difference between the medical research missions of FAA and PHS, and therefore there is substantial difference between what each agency is trying to accomplish in the conduct of these research projects.

One major concern of FAA is flying safety. As the number of aging civilian pilots grows, FAA naturally becomes concerned with the question of when does a person, because of aging, become functionally incapable of safely operating an airplane. The FAA also has a serious interest in reassessing its retirement policy in regard to FAA air traffic controllers. At present, controllers are under the regular Civil Service retirement system, but FAA has reasons to believe that a more flexible retirement policy is needed. The FAA-GCRI project is specifically aimed at this problem. It will result in the development and maintenance of standards which can be widely used in evaluating the capability of older aviation personnel to carry out their duties properly and safely.

On the other hand, the Public Health Service is interested in aging as a health problem. It is a stage of life devolving from a series of processes and body changes of which comparatively little is known. The PHS, through the Aging Program of NICHD, is attempting to increase the store of scientific knowledge concerning the aging process in humans, and to apply this knowledge to improve health services and resources for all Americans. The aim of the PHS-supported Lovelace project is to learn more about the process of physiological aging, and its progress in relation to chronological age.

On page 2, the report states "PHS is also supporting a research project on the aging of pilots. This study is being performed by the Foundation and is interested also in developing methods of measuring differences between a pilot's functional age and his chronological age." Actually the PHS study is not concerned with the aging of pilots as such but with human aging in general. The grant applications submitted on HD-00518 do not refer to the study as one dealing exclusively with the aging of pilots.

In 1964, the Foundation's application stated "It might at first sight be thought that the best approach to the investigation of the effects of aging in this professional group would be to study their actual performance as pilots. However, since our primary interest is not to assess pilot performance, the study of physiologic aging of this professional group in the laboratory is more apparently advantageous."

In the "conclusion" of the report, it is implied that NIH and FAA are "interested in a solution to the same medical problems." This conclusion is incorrect. The program on Aging of NICHD-NIH is interested in supporting any and all research which will further the understanding of the basic processes of aging in normal humans. Both the Lovelace and the FAA effort may, however, contribute to two general goals; first, the discovery of fundamental scientific information about the course of aging in humans; and second, the development of a "physiological age rating" system which would permit improvements in retirement policies for pilots and other aviation personnel. The Public Health Service is interested in the second objective only as it may contribute to the first objective. This is evident from the Study Section's comments on Lovelace's 1964 application for a grant:

"The potential contribution of this program is great, primarily because it promises to provide a large mass of well-collected data changes in functions with age—data of a kind which are presently either spotty or non-existent.

"Because of the fact that all projects (within the Lovelace group) will be collecting data on the same group of subjects, because of the frequent interaction of the several senior investigators, and because of the facilities for very extensive cross-tabulations of data from the different projects, the probability of effective cross-fertilization and integration appears high."

In the meeting in January, 1965, with the GAO staff members auditing NIH and FAA, Dr. James Birren, then Director of the Aging Program, NICHD, and also a member of the FAA medical advisory group, stated that NICHD is supporting the Lovelace effort "despite—not because of—the use of pilots as the study population. Their norms will be important scientific information even though they are not representative of the population as a whole."

An additional reason why the PHS acquiesces in the use of pilots in the Lovelace effort is that air-transport pilots represent less of an attrition or drop-out problem in a protracted study than almost any other adult group in the normal population with a comparably wide age range.

COMMUNICATIONS BETWEEN PHS, FAA, AND LOVELACE

On page 7, the report refers to the review of the Lovelace Foundation continuation grant in 1964. It says, "a PHS study group prepared a resume of the scope and nature of the work to be performed under the proposed grant and their opinion as to the desirability of continuing such work. The resume indicated that the study group was not aware of any program elsewhere duplicating this endeavor, or having the particular advantages of the present program."

The composition and the role of the so-called "study group" should be clarified. This study group was composed of distinguished non-government scientists, chosen for their expertise and stature in the field of the physiology and psychology of aging. The group, together with NIH staff members, visited the Lovelace Foundation prior to making their recommendations. At the time of the site visit, the Lovelace work was discussed by the PHS reviewers with the Lovelace staff in relation to work being done elsewhere which might tend to duplicate the Lovelace work.

The reviewers and staff of NIH were well informed of the ongoing and proposed research in both organizations. Dr. John B. Hickam, Chairman, Department of Medicine, Indiana University, was a site visitor to the Lovelace Foundation in 1961 and 1964 on behalf of NIH. Dr. Hickam informed the Aging Program Staff of NICHD that he has followed the FAA-GCRI effort since before 1961. Both Dr. Hickam and other members of the 1964 Study Section of reviewers for NIH have informed the PHS in recent telephone conversations that at the time of their 1964 site visit to the Lovelace Foundation, Dr. Proper, the principal investigator, discussed with them the work going on at FAA-GCRI, as well as the somewhat similar work going on under Dr. Nathan Shock in Baltimore, under Captain Ashton Greybiel at Pensacola, under Dr. Bourriere in Paris, etc. Dr. Hickam told us, and it is mentioned in the 1964 site visit summary statement, that he and the other reviewers were impressed by the amount of understanding of other research activities in the field of aging that the Lovelace staff demonstrated.

At the other site visits, the reviewers discussed the FAA studies with Lovelace staff and were satisfied that there were differences in design, methodology, and scope which not only set the Lovelace project apart but actually marked it to be a landmark contribution to new knowledge about human aging.

Dr. James Birren, who as Director of NICHD's Aging Program, recommended that the 1964 Lovelace application be approved by the NICHD Advisory Council has informed PHS staff that he was quite familiar with the work of both groups. Dr. Birren has worked closely with FAA staff on the scientific development and conduct of the pilot aging studies at FAA's Georgetown Clinical Research Institute, and published a scientific article in collaboration with a member of the FAA program using FAA data.

DIFFERENCES IN METHODOLOGY AND APPROACH

To the casual observer a certain amount of duplication of research may appear to exist in the conduct of these two projects. Both Lovelace and FAA are giving pilots physical and psychological examinations, and both are interested in learning more about the measurement of the aging process.

There are, however, many differences in the methods and measurement techniques used, which spring from the differences in the goals which PHS and FAA are each attempting to attain. In actual methodology, the Lovelace and the

FAA projects are, in fact, quite different. The most salient differences apparent in the two projects include these:

1. FAA conducts a rather elaborate neurological examination of each patient, including electroencephalograms, whereas Lovelace does not.
2. FAA conducts rheoencephalographic measurements (measurements of electrical impedances of the head which reflect aspects of blood flow in the brain), whereas Lovelace does not.
3. FAA conducts far more elaborate studies of vision and visual function and perception than does Lovelace.
4. FAA makes a more elaborate study of the retinal fundi than does Lovelace, and Lovelace does not take microphotographs of the retinal fundus, while FAA does this biennially.
5. FAA takes a number of biochemical and metabolic measures, while Lovelace does no work in this area.
6. FAA studies autonomic nervous system and dynamics, using the pupillary response and highly sophisticated techniques. Lovelace does not take autonomic nervous system measures.
7. Lovelace studies a variety of behavioral performance capacities rather elaborately. The FAA measures of behavioral capacities is far less elaborate, and the measurements of the two organizations are founded on rather different theoretical assumptions. The magnitude of the Lovelace effort in the behavioral capacities areas is unusual in medical research and represents a major point of interest in the Lovelace work.
8. The two organizations utilize different measures of personality structure.
9. Both organizations emphasize pulmonary and physical work studies, although their methods differ considerably.
10. Both organizations emphasize cardiovascular measures, although the two sets of measures differ considerably. For example, both organizations are working with ballistocardiography, but their approaches, equipment and methods differ considerably, and the FAA system is more elaborate. Lovelace is taking plethysmographic measures of non-cerebral peripheral blood flow, and is using radioisotopes in tracing blood flow, whereas FAA is not doing either of these things.
11. Lovelace measures lean body mass of its subject and takes a battery of anthropometric measures. These things are not done at FAA.
12. The subject-populations studied by the two organizations appear similar but actually differ considerably. Lovelace has limited its pilot sample to civil air-transport and some military pilots, who are a superselect group. FAA-GCRI studies all classes of civil aviation medical certificates, most of whom are not pilots, but are air traffic controllers. FAA also studies some older, former aviation personnel.
13. FAA subjects are examined more frequently (each year or each second year) than the Lovelace subjects, who are to be examined once each five years. Lovelace intends to examine 500 men periodically. FAA has examined about 1,500 subjects at least once, although it appears that a somewhat smaller number will be examined on a periodic basis.

There are several other differences of this nature which could be added to this list, but these are the major ones.

DUPLICATION OF RESEARCH EFFORT

In general, the report demonstrates that the GAO investigators did not understand what is and what is not duplication in medical research. GAO staff was assured by NIH staff that the possibility of unnecessary duplication of effort was considered as the grant was reviewed, and that it was the determination of the reviewers and NIH staff that the Lovelace effort did not duplicate research conducted by FAA, or NIH's Gerontology Branch or other research being conducted in Europe. Rather, it was the determination of these reviewers that the Lovelace project was quite unique.

Further, the report indicates a lack of understanding of NIH's processes for reviewing research grant proposals which have built-in controls to prevent unnecessary duplication of effort.

One control is found in the heavy reliance upon peer judgment. All grant applications are reviewed by a competent group of researchers who are working or are familiar with the discreet field or discipline in which the proposed research will be conducted. These experts are aware of the state of the art in the field as well as ongoing work. They generally are quite critical of unnecessary duplication. Dr. John Sherman, NIH Associate Director for Extramural Programs,

addressed himself to this point in a recent letter to Senator Everett Dirksen (April 1965), which is quoted in part below:

"All applications to the National Institutes of Health for research grant funds are carefully reviewed by two groups of outstanding non-federal experts. These groups are highly informed concerning past and present research activities in the field of their concern, and they would not approve requests which involved unnecessary duplications of previous work. *What sometimes seems to be a duplication usually turns out to represent alternative approaches to an unsolved research problem.* It should also be pointed out that scientists achieve the approval of their peers and advancement in their research career through performing original research work, not through repetition of work already performed. Therefore, there is no motivation for any scientist to duplicate experiments, the results of which have already been well established in the scientific community." [Italics added (in the text of response).]

Another inherent control to prevent the support of unnecessary duplication of effort by PHS-supported investigators is that little professional stature is accorded to the scientist who engages in unnecessary duplication. Investigators, therefore, do not seek support for research which is not original and would not enhance their professional standing.

CONCLUSIONS

The draft report currently under consideration contains many deficiencies and omissions of fact.

Because its recommendations are based on these deficiencies and omissions of fact, the Public Health Service disagrees with both the statements of findings and the recommendations. On the contrary, the PHS maintains that scientific coordination in the conduct of these two research projects has been, and will continue to be, close and productive of the highest caliber of scientific achievement. The facts brought out in this case support, rather than negate, the effectiveness of the dual peer review grant-in-aid mechanism in preventing unnecessary duplication of research effort. The recommendations in the draft report are therefore pointless.

ATTACHMENT No. 1

HISTORY OF HD-00618

The following is a chronological history of the Lovelace Foundation grant as submitted to the PHS:

February 1960: Lovelace Foundation application submitted to NIH, and numbered RG-7646. Application was for \$200,000 per year for 5 years plus indirect costs.

May 1960: RG-7646 reviewed by special study section, which conducted a site visit. Study section recommended disapproval with advice to NIH staff to communicate with Lovelace. The principal reasons for disapproval was the imminent departure from Lovelace of the co-investigator, Dr. Estes, the lack of sufficient emphasis on biomathematical staff to properly capture and manipulate the data to be gathered, and the lack of clarity regarding the phasing of the project.

June 1960: The National Advisory Health Council concurred with study section recommendations.

February 1961: Lovelace resubmitted application after communication with staff of the Division of General Medical Sciences. Support of approximately \$160,000 per year for five years was requested. This application noted their conduct of a planning study, under contract, for FAA, and that they had made preliminary recommendations concerning the study of aging in pilots only.

April 1961: RG-7646 again reviewed by special study section, after a site visit, recommended approval for only three years at \$75,000 per year. Study section suggested that, in order to develop a sound basis for a long-term study, that the grantee begin research on a small table group of subjects, namely air transport pilots; and then expand the study in three years if the study proved to be productive.

June 1961: The National Advisory Health Council concurred with study section recommendation.

October 1961: RG-7646 activated.

October 1963: RG-7646 transferred from National Institute of General Medical Sciences to NICHD and re-numbered HD-00518.

January 1964: Lovelace submitted an application for a continuation of support for five years at \$162,000 per year. The application proposed an expansion of the research subject population beyond that of transport pilots, as a commencement of the longitudinal phase.

April 1964: Application was reviewed and site visited by the NICHD Program Projects Committee which recommended full support.

May 1964: National Advisory Child Health and Human Development Council concurred with study section recommendation.

October 1964: Continuation of HD-00518 activated.

June 1965: Lovelace submitted a supplemental application for support of additional data processing equipment, amounting to \$36,000.

October 1965: NICHD Program Projects Committee recommended approval of supplemental.

December 1965: National Advisory Child Health and Human Development Council concurred with study section recommendation.

The reviewers participating in each NIH project site visit are listed in Attachment No. 2. In addition to the non-government experts, NIH staff was present at each visit.

ATTACHMENT No. 2

SITE VISITORS

RG-7646, HD-00518

May 1960: Dr. Jacob E. Bearman, University of Minnesota; Dr. Wilse B. Webb, University of Florida; Dr. Earl T. Carter, Ohio State University; Dr. James Warren, University of Texas Med; Dr. Stewart G. Wolf, University of Oklahoma; Dr. Jerome Cornfield, Johns Hopkins University; Mrs. Olive Meader, National Institutes of Health.

May 1961: Dr. John B. Hickam, University of Indiana; Dr. David Graham, University of Wisconsin; Dr. Jacob Bearman, University of Minnesota; Mrs. Olive Meader, National Institutes of Health.

April 1964: Dr. Lowell Kelly, University of Michigan; Dr. Rich McHugh, University of Minnesota; Dr. John Hickam, University of Indiana; Dr. David Graham, University of Wisconsin; Dr. Edelberg, University of Oklahoma; Dr. Margaret T. Goldsmith, National Institutes of Health; Mr. Rolf Versteeg, National Institutes of Health.

ATTACHMENT No. 3

MEMORANDUM

FEBRUARY 5, 1965.

To: The record.

From: Staff assistant for program, Aging Program, NICHD.

Subject: Meeting with G.A.O. officials to discuss grant No. HD 00518.

Late in the afternoon of January 26, I received a telephone call from Mr. Harry Sanger of the General Accounting Office located at NIH. He informed me that he would like to discuss the research grant awarded to the Lovelace Foundation, which is Grant No. HD 00518-04 entitled "Study of Physiological and Psychological Aging," being supported by NICHD and administered by the Aging Program. He asked to schedule an appointment with me for January 26 at 9:00 A.M. due to the absence of Dr. Birren, Aging Program Director, who was out of town and since I had accompanied the site visit team at their site visit on May 11, 1964 in Albuquerque. I scheduled this appointment with Mr. Sanger who said he would also be accompanied by Mr. Robert Burns of the GAO located at the Federal Aviation Agency, and I notified Mr. Baldwin and also contacted Mr. Chicchirichi whom I asked to be present at the meeting.

The meeting on January 27 at 9:00 A.M. had Mr. Sanger, Mr. Burns, Mr. Chicchirichi, and myself present and lasted about an hour and a half. The primary issue brought out for discussion by Mr. Sanger and Mr. Burns was that a study on the psychological and physiological capacities of pilots was being conducted by the Georgetown research unit of the Federal Aviation Agency which appeared to be similar to the study being conducted by the Lovelace Foundation for Medical Education and Research under Grant No. HD 00518 awarded by the NICHD in amounts ranging from \$162,500 to \$131,000 a year for five years beginning with the fourth year of the previously awarded grant.

Mr. Sanger and Mr. Burns asked specifically whether we were concerned about duplication of research work and also whether we and the review group were

aware of the research of a similar nature being conducted by the FAA. I replied that we are very much concerned and interested in eliminating unnecessary and unintentional duplication in research, and that in furthering this objective we are in the process of establishing an Aging Information Center to be administered by this Institute which will use automated systems for the storage and dissemination of information concerning the research that has been and is being conducted in the field. I also pointed out that in science, research is sometimes purposely and necessarily duplicated for various reasons such as corroborating the procedures and results of studies, and using different methods and techniques on similar or related problems. I mentioned that in the Lovelace Foundation Study for example, they were utilizing unique methods and techniques for determining body fat-free weight consisting of underwater weighing, and also that they were considered to have exceptionally well qualified individuals to design and conduct the studies such as their physiologist, Dr. Luft and their psychologist, Dr. Szafran. I also responded that we were aware of the related study being conducted by the FAA scientists and that Dr. Birren is in touch with some of the FAA investigators on this study and we receive copies of their publications. Mr. Chicchirichi pointed out that the FAA study was referred to in a summary sheet of a previous project site visit. I indicated that I did not know exactly the extent and depth of Dr. Birren's knowledge of the FAA study. The GAO officials then said they would like to discuss this point with Dr. Birren personally, and an appointment was made for 9:00 A.M. the next morning.

On January 28 at 9:00 A.M. Mr. Sanger and Mr. Burns met with Dr. Birren, Mr. Chicchirichi and myself. Dr. Birren was asked to compare the Lovelace Foundation Study to the FAA study and he described the FAA study and stated that it was broader in scope with respect to clinical neurology including the use of EEG, visual function involving the pupil, the ballistocardiograph, and behavioral measurements of deficit.

He said that since it started earlier, around 1957-1958, it may have served as a model for the Lovelace Foundation Study. Dr. Birren added that in the Lovelace study the various physiological and psychological measurements are approached differently although the general objectives of the two studies are similar, but in those areas where there is similarity this is desirable because so little is known about these measurements. Dr. Birren said that Lovelace has aspects in their study such as research on respiratory function which is not contained in the FAA study due to the shortage of scientific personnel qualified in this area of competence. Dr. Birren indicated that the Lovelace study involved important research which would yield valuable information and that we are supporting this study despite of—not because of—the use of pilots as the study population who represent a sample of healthy men. Their norms will be important information even though they are not representative of the population as a whole. The GAO officials informed us that the FAA asked the Lovelace Foundation to undertake a feasibility study on determining aging factors related to physiological and psychological capacities and then proceeded to conduct their own study. The GAO officials did not elaborate on the content of the feasibility study or the nature of the terms and restrictions of the contract awarding the study. Dr. Birren expressed his interest in learning more about the legal significance and the relationships of the feasibility study to both the FAA and the Lovelace Foundation research projects.

ROLF VERSTEEG.

