Robert E. Shank Papers

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Consumer Protection & Environmental Health Service
National Air Pollution Control Administration
Arlington, Virginia 22203

FOR RELEASE IN P.M. PAPERS HEW-V9
Saturday, September 21, 1968

The National Air Pollution Control Administration (NAPCA) today announced that the Tennessee Valley Authority has completed a NAPCA-sponsored design study of the dry limestone injection process for control of sulfur oxide emissions from electric power plants.

The design study is a further step in the continuing Federal research and development program concerned with the control of sulfurous air pollution.

NAPCA Commissioner John T. Middleton said that TVA will use the results of the just-completed study in planning full-scale tests of the limestone injection process at its Shawnee and Paradise power plants in Kentucky in 1969.

Commissioner Middleton explained that the limestone injection process offers a number of advantages to industry because of its relative simplicity. Considerable further research is needed, however, to improve the presently limited ability of limestone to react with sulfur dioxide in stack gases. The TVA tests scheduled for next year are expected to provide much information on the variables that affect limestone's ability to pick up and hold sulfur dioxide.

The TVA report on the study conducted in cooperation with NAPCA includes both technical and economic evaluations of the limestone injection process. It describes presently available technology, the effects of the process on power plant operation, equipment needed for its application, and summarizes current research in the United States and abroad as well as future research needs.

The 91-page TVA report is available for a price of $3.00 from the Clearinghouse for Federal Scientific and Technical Information, Springfield, Va. 22151. It should be ordered by number and title: PB 178972 - Sulfur Oxide Removal From Power Plant Stack Gas.

# # #

CONTACT [illegible]
(Home) [illegible]

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
Health Services and Mental Health Administration
National Clearinghouse for Smoking and Health
Arlington, Virginia 22203

FOR RELEASE IN A.M. PAPERS
Tuesday, September 17, 1968

HEW-75

Five ways to reduce the health risks of cigarette smoking are presented in a new Public Health Service pamphlet issued today.

Titled, "If You Must Smoke," the pamphlet was prepared by the National Clearinghouse for Smoking and Health, an agency of the PHS's Health Services and Mental Health Administration.

About a million and a half Americans swear off smoking each year, the pamphlet says, yet tens of millions continue to smoke, either because they are unable or unwilling to quit.

To help smokers "slow down" the harmful effects of smoking, the leaflet suggests five things they can do. However, smokers are first reminded that doing these things will not make smoking safe. "Anything you may do short of quitting completely is merely a compromise," the pamphlet warns.

The five positive steps recommended to lower one's intake of cigarette smoke are:

"1. Choose a cigarette with less tar and nicotine . . . . Learn the tar and nicotine content of your cigarette . . . . See how your brand compares and find out how much you may reduce your tar and nicotine intake by switching to another brand, or to another version of the brand you are presently smoking. Will such a switch result in your smoking more? Probably not. Most smokers who make such a change either continue to smoke at their previous rate or even smoke less.

"2. Don't smoke your cigarette all the way down. No matter which cigarette you smoke, the most tar and nicotine is found in the last few puffs . . . So the sooner you put your cigarette out, the fewer your dose will be of harmful ingredients. This same fact also points up the added risk of the new 'longer' cigarettes. Their 'extra puffs' are really 'extra perils' for you.

"3. Take fewer drags on each cigarette . . . With practice, some people find they can substantially cut their actual smoking time without really missing it.

"4. Reduce your inhaling. Hunter said that also? Perhaps. But remember it is the smoke which enters your lungs that does most of the damage . . . And it is this smoke that creates the cardiovascular changes which can bring on heart attacks.

"5. Smoke fewer cigarettes per day . . . Pick a time of day when you promise yourself not to smoke. It may be before breakfast. Or while driving to work. Or after a certain hour each evening. It's always easier to postpone a cigarette if you know you will be having one later. Maybe you're a pack-a-day smoker. Try buying your next pack an hour later each day. It may also help to carry your cigarettes in a different pocket. Or, at work, keep them in a drawer of your desk or in your locker--any place where you aren't able to reach for one automatically. The trick is to change the habit patterns you have established. Make a habit of asking yourself, 'Do I really want this cigarette?' before you light up. You may be surprised at how many cigarettes you smoke you don't really want."

Single copies of "If You Must Smoke," (PHS Publication No. 1706) are available without charge from the National Clearinghouse for Smoking and Health, 4040 North Fairfax Drive, Arlington, Virginia 22203. The pamphlet may be purchased in quantity from the Superintendent of Documents, U. S. Government Printing Office, Washington, D.C. 20402, at five cents a copy or $3.25 per 100.

# # #

July 3, 1968

Mr. Keith Kost
Executive Editor
Public Health Reports
North Bethesda Office Center
Building 2, Room 28
Public Health Services
Chevy Chase, Maryland 20015

Dear Mr. Kost:

I have reviewed the paper entitled "Prevalence of Rheumatic Fever and Rheumatic Heart Disease in United States College Freshmen, 1956-1965." My comments and opinions are attached.

I was interested in reading the manuscript and hope that it may be published.

Very sincerely yours,

Robert E. Shank, M. D.

Enc

"Prevalence of Rheumatic Fever and Rheumatic Heart Disease
in United States College Freshmen, 1944-45"

by

Lowell Ferry, J. H. Pettes, and C. Findlay

The paper presents data and information of considerable interest and importance relative to the prevalence of rheumatic heart disease. The group studied (college freshmen) is pertinent for assessment of the risks pertaining to rheumatic fever in early life. However, as pointed out by the authors, it cannot be considered as a representative population sample of this age. It is selected with bias relative to male sex and to economic status. Nevertheless, the data derived are probably of greatest significance relative to changes with time. The conclusions which are drawn seem to be warranted by the data as described.

This reviewer takes exception to the claim of the authors on page 9 that evidence supports a three-fold increase in rheumatic heart disease prevalence during adulthood in the period from 1936 to 1944. In one instance data are drawn from the population of Framingham, Massachusetts, while the comparative data are apparently taken from physical examinations of military inductees (references 30 to 33). The populations compared probably differ in many respects but most importantly in states of residence and socio-economic status. Therefore, I believe that the paper is weakened by this inclusion.

Certainly, if this section is published, the authors should offer better defense of their argument and the specific conclusion of a three-fold increase in prevalence from the approximate age of 25 to 50 years.

On the whole I consider that the paper merits publication but would hope that some change might be made in the paragraph on page 5.

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
~~Bethesda, Maryland 20014~~
Chevy Chase, Maryland 20015

Manuscript Review Request

TO: Dr. Robert E. Shank, Department of Preventive Medicine, Washington University School of Medicine
660 S. Euclid Avenue, St. Louis, Missouri 63110

Date: June 25, 1968

From: Executive Editor, PUBLIC HEALTH REPORTS, North Bethesda Office Center Building 2, Room 28
Keith Kent mp

Title: "Prevalance of Rheumatic Fever and Rheumatic Heart Disease in United States College Freshmen, 1956-1965"

PHR Number: 8-90

Author(s): Lowell W. Perry, M.D., et al.

The enclosed manuscript is being considered for publication in PUBLIC HEALTH REPORTS. It would be deeply appreciated if you can spare the time to read it and let us have your comments.

Mark the copy if you wish. It will be particularly helpful if you send us your comments on separate sheets, in duplicate; one for our staff and one for the author.

Your identity will not be revealed to the authors, unless you prefer to identify yourself. You may do so by signing a carbon copy of your remarks.

Comment freely according to your general reaction. You may also wish to discuss specific criteria that apply, such as:

Basic accuracy and validity
Appropriateness and application of methods and procedures
Logic and soundness of conclusions
Clarity
Extent and usefulness of references
Extent and usefulness of illustrative material, charts, and tables
Value of paper to public health workers

We hope we may have your comments by July 10, 1968. We shall also welcome comments by your associates.

Use the enclosed envelope to return your comments, the manuscript, and this identifying letter.

Our sincere thanks and appreciation.

NOTE: After technical and professional review, this paper will be checked for style, grammar, spelling, and construction by our staff.

6/6/68

Mental Health Epi

questionnaire

Dr. ~~Z~~ Zussman office

~~[illegible]~~

NH ~~[illegible]~~ I Mental Health

sent in April 4 sides to put.

area code 301
496-0237 Miss Hannon

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF MENTAL HEALTH
5454 WISCONSIN AVENUE
CHEVY CHASE, MARYLAND 20203

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8A15

Dr. Jack Zusman, Chief
Center for Epidemiologic Studies
National Institute of Mental Health
5454 Wisconsin Avenue
Chevy Chase, Maryland 20203

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

April 5, 1962

Dr. Robert Shank
Department of Preventive Medicine
Washington University
School of Medicine
660 South Euclid Street
St. Louis, Missouri 63110

Dear Dr. Shank:

I have two purposes in sending you this letter. The first is to let you know about the establishment within the National Institute of Mental Health of a Center for Epidemiologic Studies. The Center is intended to provide a new emphasis for the Institute's concern with the study of the epidemiology of mental health and mental illness. The Center is prepared to review and fund applications for research or for training grants. It will undertake to provide limited consultation regarding epidemiologic projects and, in certain instances, to collaborate in the conduct of investigations.

My second purpose in writing to you is to invite your assistance in formulating a program for training in mental health epidemiology. As a preliminary to developing such a program we need to know:

1. Where training in mental health epidemiology is currently offered (e.g., Departments of Psychiatry and Preventive Medicine in Medical Schools, Schools of Public Health, Departments of Behavioral Sciences, Schools of Social Work, etc.)?

2. How this training is presented (e.g., Electives, identifiable courses or seminars, as a part of some other course, as an integral part of a core curriculum leading to a degree)?

3. What courses are taught (e.g., how many courses are available, what is the content of the courses, are they required or elective, etc.)?

4. What students are enrolled in the courses (e.g., the number of students, from what professions, working toward what degrees)?

5. What is the extent of the shortage of qualified teachers of mental health epidemiology (e.g., is the number of qualified teachers of mental health epidemiology insufficient to permit enriching or enlarging curricula? Is there a problem securing persons trained to practice mental health epidemiology? Is this because a sufficient number of individuals are not or cannot be trained by the schools)?

I am enclosing a survey questionnaire which incorporates the queries to which we hope that you and your associates will reply. For the purpose of this survey we wish to include any teaching that involves one or more sessions of formal instruction on epidemiological, ecological or sociological factors in mental or emotional disorders or in mental health. We recognize that a fair amount of teaching goes on as part of courses which are labelled in the catalog as neither epidemiology nor mental health. It is information about such teaching that we are particularly interested to have.

We expect the information which we receive from the survey will allow us to proceed more knowledgeably with the task of developing diversified and useful training programs. We are eager to have your counsel on what you regard as fruitful ways of inaugurating training programs at levels ranging from basic orientation to those producing a high degree of technical mastery of the field.

We urgently request your immediate help in the prompt return of the enclosed form. You are welcome to write or call us about this survey or any other issues involving the Center's area of responsibility. Naturally, you are free to consult any members of your staff in completing the form. We appreciate your cooperation in this survey, as well as any suggestions you may wish to make of persons who might like to be placed on the mailing list of the Center for Epidemiologic Studies.

Sincerely yours,

Jack Zusman

Jack Zusman, M.D.
Chief
Center for Epidemiologic Studies

Enclosures

NAME OF INDIVIDUAL COMPLETING QUESTIONNAIRE

Dr. Robert Shank
Dep't of Preventive Medicine
Washington U. Sch. Medicine
660 South Euclid Street
St. Louis, Missouri 63110

TITLE

INSTRUCTIONS: For Items 1 through 5 please list title and course number of each course in which any mental health epidemiology teaching occurs or the type of traineeship. For each course or type of traineeship listed please complete the information requested in each column.

	TITLE AND NO. OF COURSE OR TYPE OF TRAINEESHIP	SEMESTER OFFERED OF WHAT TRAINING YEAR	DEPARTMENT WHERE TAUGHT	ELEC-TIVE	RE-QUIRED	SESSIONS	
						Total No. In Course	No. Devoted To Mental Health Epi.
EXAMPLE	Psychiatric Residency	2nd 1/2 of 1st year of residency	Psychiatry		X	24	2
EXAMPLE	Psychiatry 306	1st 1/4 of 3rd year medical school	Psychiatry	X		36	4

1. Courses Which Include Teaching in Mental Health Epidemiology

If none, check box and go to page 2, Items **4A1** and **4B1.** ☐ NONE

TITLE AND NO. OF COURSE OR TYPE OF TRAINEESHIP	SEMESTER OFFERED OF WHAT TRAINING YEAR	DEPARTMENT WHERE TAUGHT	ELECT-TIVE	RE-QUIRED	SESSIONS	
					Total No. In Course	No. Devoted To Mental Health Epi.

2. Content of Courses (Give brief description of mental health epidemiology subject covered)

If courses are adequately described in catalog, list title and number only. Repeat listing of courses as given in Item 1.

TITLE AND NO. OF COURSE OR TYPE OF TRAINEESHIP (List courses)	

3. Methodology of Training in Mental Health Epidemiology

(Please check all methods used. List courses as given in Item 1)

TITLE AND COURSE NO. OR TYPE TRAINEESHIP (List courses as given in Item 1)	LECTURE	SEMINAR	FIELD WORK	FIELD VISIT	INDIVIDUAL RESEARCH	TUTORIAL	INSTITUTES	OTHER (Specify)

4 A. Number of Post-Baccalaureate Students Registered for Course in Academic Year 9/67 to 6/68 by Profession

On line 4A.1 please give total number of students in your department (or school for nursing and social work) by profession.

(Specify number in each semester, if different)

TITLE AND COURSE NO. OR TYPE TRAINEESHIP (List courses as given in Item 1)	DISCIPLINE — Enter number of post-baccalaureate students in each discipline who registered for course									
	M D			NURSE	PSYCHOL-OGIST	SOCIOL-OGIST	ANTHRO-POLOGIST	SOCIAL WORKER	OTHER (Specify)	NOT KNOWN
	Under-grad.	Graduate: Resid. Trainee	Graduate: Not Resid. Trainee							
4 A.1 TOTAL NO. STUDENTS IN DEPARTMENT:										

B. Number of Post-Baccalaureate Students Registered in Academic Year 9/67 to 6/68 by Degree For Which Registered

On line 4B.1 please give total number of students in your department (or school for nursing and social work) by degree.

(Please enter number of students in appropriate column)

TITLE AND COURSE NO. OR TYPE TRAINEESHIP (List courses as given in Item 1)	MD	PUBLIC HEALTH		SOC. SCI. & SOC. WORK		NURSING		RESIDENCY TRAINING		OTHER		NO DEGREE
		Masters	Doctor-ate	Masters	Doctor-ate	Masters	Doctor-ate	Psycht.	Prev. Med.	Masters	Doctor-ate	
B.1 TOTAL NO. STUDENTS IN DEPARTMENT:												

5. Teaching Materials

(Please check all appropriate columns. Be sure to include available copies of materials used)

TITLE AND COURSE NO. OR TYPE TRAINEESHIP (List courses as given in Item 1)	TEXTS	BIBLIO-GRAPHIES	AUDIO-VISUAL AIDS	CASE MATERIALS	OTHERS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF MENTAL HEALTH

SURVEY OF TEACHING OF MENTAL HEALTH EPIDEMIOLOGY

DEFINITIONS AND INSTRUCTIONS

MENTAL HEALTH EPIDEMIOLOGY

The Center for Epidemiologic Studies defines mental health epidemiology as the scientific study of the incidence, course, and patterns of mental illness and mental health in defined populations for the purpose of understanding primary and contributory causes of mental illness or health. Mental health epidemiology includes ecological study of the interaction of biological, social, environmental and other factors which determine mental disease or health; the study of the natural history of mental illnes; evaluation of the effectiveness of mental health programs serving defined populations; and the study of social institutions and processes established to prevent and treat mental illness insofar as these influence case definition and course of illness.

For the purpose of this survey, we ask that you include alcoholism, behavior disorders, drug addiction, mental retardation and suicide within the scope of mental disorders. We are interested to know of direct teaching of mental health epidemiology in medical schools, schools of public health or elsewhere, as well as the application of epidemiologic principles to problems of mental health or mental illness by other disciplines than medicine. Please report any teaching which involves at least one or more sessions bearing on mental health epidemiology as defined.

GENERAL INSTRUCTIONS

IF YOUR DEPARTMENT HAS COURSES IN MENTAL HEALTH EPIDEMIOLOGY AND HAS NO PLANS TO INTRODUCE NEW COURSES

Please complete all questions in questionnaire according to instructions on questionnaire.

IF YOUR DEPARTMENT HAS COURSES IN MENTAL HEALTH EPIDEMIOLOGY AND PLANS TO INTRODUCE NEW COURSES IN NEXT THREE YEARS

Please complete all questions in questionnaire according to instructions on questionnaire. List the courses you already offer in mental health epidemiology. Below the names of courses you are currently offering, list the titles of courses you expect to introduce within the next three years. Underscore the titles of these projected courses so as to distinguish them from those already in your curriculum. State in parentheses in the lefthand margin the date on which you anticipate that the projected courses will become operational. Give all information on these courses which is requested in questions 1, 2, 3, and 5.

IF YOUR DEPARTMENT HAS NO COURSES IN MENTAL HEALTH EPIDEMIOLOGY AND HAS NO PLANS TO INTRODUCE NEW COURSES

Please check X in the box "None" above question 1, and omit questions 1, 2, 3, 5, 6, 11, 12, and 13.

Please answer questions 4A.1, 4B.1, 7, 8, 9 and 10.

IF YOUR DEPARTMENT HAS NO COURSES IN MENTAL HEALTH EPIDEMIOLOGY AND PLANS TO INTRODUCE NEW COURSES IN NEXT THREE YEARS

Please complete all questions according to instructions on questionnaire. In question 4, you can only complete parts 4A.1 and 4B.1. Underscore the titles of projected courses and state in parentheses in the lefthand margin the date on which you anticipate that the projected courses will become operational.

Please send copies of catalogs, annual reports, brochures, etc. which describe the courses or traineeships you report. If readily available, please also include copies of bibliographies as requested in question 5, as well as manuals, lecture notes, case materials, syllabi, discussion guides or audio-visual aids, etc.

MH-111
3-68

Budget Bureau No. 68-S68007
Approval Expires: 12-31-68

6. **FACULTY** (Please give information for each key instructor, beginning with the senior faculty member. Attach additional sheets if necessary)

If training is clearly indicated in catalog, give only experience in teaching and research.

NAME AND TITLE	TRAINING SCHOOL: Institution, degree(s) FIELD : Internship, Residency (Institution, location, duration)	EXPERIENCE

YOUR OPINION ON ITEMS 7 through 13 IS VERY IMPORTANT FOR PLANNING THE PROGRAM OF THE CENTER FOR EPIDEMIOLOGIC STUDIES. PLEASE ANSWER EVERY QUESTION FULLY AND USE AN ADDITIONAL SHEET IF NECESSARY.

7. **Of what benefit do you think knowledge of mental health epidemiology can be to students whom you train?**	
8. **Ideally, what emphasis should mental health epidemiology have in your department** (e.g., goals of teaching, relative time available for teaching, which students should take, elective or required, etc.)?	
9. **What courses and/or opportunities for field work should be provided in an adequate training program in mental health epidemiology?**	
10. **Would a broader training program in mental health epidemiology than is currently available in your department be desirable?** ☐ No ☐ Yes	If yes, specify what is necessary to secure this (e.g., change in attitudes or policies of other departments, money, staff, additional facilities, etc.)
11. **Would additional faculty and staff be needed in order to provide an adequate program in mental health epidemiology in your department?** ☐ No ☐ Yes	If yes, specify number needed by profession.
12. **Would additional students be desirable if your department were to provide a broader program in mental health epidemiology?** ☐ No ☐ Yes	If yes, specify number desired by profession.
13. **What training courses, or teaching materials and aids would be of help to faculty members currently teaching mental health epidemiology in your department?** ☐ No Training Needed	☐ Training Needed. (Specify if summer courses for weeks, packaged lectures and discussion guides, bibliographies, etc.)

TO: Deans, Directors, and Department Chairmen
FROM: George W. Hazzard
For your information.

Higher Education and National Affairs

American Council on Education • 1785 Massachusetts Avenue, N.W., Washington, D.C. 20036

Howe Assails House Vote To Bar Funds to Rioters

* * *

Senate Panel Urges NSF To Boost Sea Grant Effort

Volume XVII, Number 19 **May 24, 1968**

File N.I.H Policy

HEW Comptroller Spells Out Details of Grant, Contract Suspension

James F. Kelly, assistant secretary and comptroller of the Department of Health, Education, and Welfare spelled out in detail this week for HEW administrators instructions for the current suspension of awarding grants and contracts. HEW officials ordered the suspension in view of Congressional efforts to cut $6 billion in spending for Fiscal Year 1969 (see *Bulletin,* Vol. XVII, Nos. 17 and 18).

In his May 22 memorandum, Kelly lists eight specific instructions to be followed within HEW. Following is the complete text:

This will confirm, clarify and partially modify the oral instructions to temporarily suspend fund commitments.

As you know, the Congress has under active and serious consideration a bill (HR 15414) which is designed to effect reductions during fiscal year 1969 in new obligational authority, expenditures, staffing, and rescission of carryover funds. The amount of the proposed reduction in new obligational authority and expenditures, particularly expenditures, is such as to indicate very substantial program impact. A considerable portion of the controllable expenditures from general revenues incurred by this Department each year relate to payments for obligations incurred in the prior year or years.

In order that we might make plans which take into consideration all of the options available to us, the Secretary has requested that we suspend all approvals and commitments of loans, grants and program contracts, and the authorization to start construction of HEW direct and assisted projects pending an assessment of the problem and the development of plans to cope with a major expenditure reduction should this become necessary.

The following instructions are designed to carry out the Secretary's request:

1. Non-competing continuation grants (those with a moral commitment to continue, as first call on available funds) may be awarded without interruption in project operations.

2. Contract renewals which equate with non-competing continuation grants (i.e., those with a firm moral commitment to continue, as first call on available funds) may be approved without interruption in project operations.

3. Grants or contracts which are essential to the provision of direct medical care of Federal beneficiaries may be awarded without restriction.

4. Procurement contracts for normal, recurring supplies, maintenance, and operation may be awarded and purchases against existing contracts of this type may be made.

5. New and competing grants and contracts may not be awarded. No notice of award or intent to award is to be made.

6. Grants and contracts for traineeships and fellowships shall cover only enrolled students for second and subsequent years—not new students—pending completion of the reassessment now underway.

7. No new construction grant or contract award shall be made except that steps will be taken to assure that funds are not lapsed because of temporary delay occasioned by HEW actions. Awards made to avoid lapsing of funds should make clear that there is no commitment as to when construction can be started.

8. Authorization to advertise for construction bids will be suspended. However, requests for authorization to go to bid for construction grants, loans and direct operations should continue to be submitted in the normal manner.

Every effort will be made to reach decisions on a future course of action by early June. You will be kept informed of developments.

In a letter to two Senators May 23, HEW Secretary Wilbur J. Cohen explained his reasons for the suspension as follows: "No decision has been made on the allocation of the reduction but it is reasonable to estimate for planning purposes that a $6 billion expenditure reduction might require a reduction of $700 million to $1 billion in HEW. This would require a reduction of 21 percent to 30 percent in 1969 controllable programs unless steps could be taken which would permit some of the reduction to be taken against the $3.4 billion in expenditures estimated to be required to pay for obligations incurred in prior years or out of prior year funds. The prospect of a reduction of this magnitude and its impact on the important and necessary programs administered by this Department placed upon me a special responsibility to thoughtfully and carefully plan our programs so as to minimize as far as possible the adverse impact of such a reduction. . . ."

May 21, 1968

Public Inquiries Branch
U. S. Public Health Service
Washington, D. C. 20201

Gentlemen:

As per the PHS release dated May 20, 1968, I would like to request a copy of the two publications mentioned.

1) the programmed instruction manual
(PHS Publication No. 1468-A)

2) the related reference booklet
(PHS Publication No. 1468)

I shall very much appreciate receiving these two booklets. Thank you!

Sincerely yours,

Robert E. Shank, M. D.
Dept. of Preventive Medicine
Washington University
School of Medicine
4550 Scott Avenue
St. Louis, Missouri 63110

P.S. The publication is titled "Legal Aspects of PHS Medical Care - A Programmed Instruction Course."

Rec'd 5/31/68

FURLONG--495-5608
(Home) --277-2621

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Health Services and Mental Health Administration
Bureau of Health Services
Silver Spring, Maryland 20910

FOR RELEASE TO PROFESSIONAL JOURNALS
Monday, May 20, 1968

A self-instruction publication titled, "Legal Aspects of PHS Medical Care - A Programmed Instruction Course," was announced today by the Health Services and Mental Health Administration of the Public Health Service. It is a companion piece for use with a reference booklet by the same title.

The material is intended to show legal obligations and barriers that PHS physicians and other medical-health personnel face when they treat patients in facilities of the Public Health Service. However, non-Governmental medical people meet many of the same problems in the private practice of medicine. The two manuals should prove helpful to physicians generally, administrators of all medical facilities, nurses, other providers of medical care, and students of public health.

The programmed instruction format of the new manual is a teaching device that combines explanations and test questions to set the stage for easy learning by busy readers. The author, Eli P. Bernzweig, of the PHS Bureau of Health Services, states that none of the material is intended to give definitive legal advice to solve specific legal problems. Instead, readers are given broad legal considerations involved in the provision of medical care.

Both publications are on sale from the Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402. The programmed instruction manual (PHS Publication No. 1468-A) is 55 cents. The related reference booklet (PHS Publication No. 1468) is 50 cents. Single free copies are available from Public Inquiries Branch, U. S. Public Health Service, Washington, D. C. 20201.

Write for both

# # #

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
REGIONAL OFFICE VI
601 EAST 12TH STREET
KANSAS CITY, MISSOURI 64106

PUBLIC HEALTH SERVICE

May 17, 1968

Robert E. Shank, M.D.
School of Medicine
Washington University
660 South Euclid
St. Louis, Missouri 63110

Dear Doctor Shank:

Attached is a copy of a policy statement which became effective November 8, 1967 and is applicable to all grant, contract, and loan funds provided from current appropriated funds.

D.S. NOTE

It should be noted that the primary responsibility for complying with this action rests with the recipient who should notify his affiliates, sub-contractors, and others of this provision, and inform them of their responsibilities under this provision.

Sincerely yours,

John M. Whitney, M.D.

John M. Whitney, M.D.,
Regional Health Director

Enclosure

✓ ~~Dr. Shank~~
✓ ~~Dr. Chaplin~~
✓ ~~Dr. Peden~~
✓ Dr. Morrison
✓ Dr. Kellogg
✓ ~~Dr. Osterland~~
✓ ~~Dr. Lindquist~~
✓ ~~Dr. J. B. Fleischman~~

Please read - check your name - & then pass on to the next person. Return to Dorothy after all have read this.

NOTICE TO ALL RECIPIENTS OF GRANTS, LOANS AND CONTRACTS AWARDED BY OPERATING AGENCIES OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Section 907 of the Department's Appropriation Act of 1968 (P.L. 90-132) provides:

> No part of the funds appropriated under this Act shall be used to provide payments, assistance, or services, in any form, with respect to any individual convicted in any Federal, State, or local court of competent jurisdiction, of inciting, promoting, or carrying on a riot, or any group activity resulting in material damage to property or injury to persons, found to be in violation of Federal, State, or local laws designed to protect persons or property in the community concerned.

This provision which became law on November 8, 1967, is applicable to all grant, contract, and loan funds provided from current appropriated funds. Payments, assistance or services may not be provided from such funds to any employees of grantees or contractors, or to any recipient of a fellowship, borrower, or other beneficiary of a grant program providing services or assistance, who has been convicted in a Federal, State, or local court of competent jurisdiction, subsequent to November 8, 1967, on any of the following offenses:

a. inciting, promoting, or carrying on a riot;

b. any group activity resulting in material damage to property of injury to persons

if the activity has been found to be in violation of laws designed to protect persons or property in the community concerned.

The primary responsibility for observing and complying with the limitations of Section 907 of P.L. 90-132 rests with the recipient of the grant or contract or the administrator of any loan program under funds provided from such appropriation. Each grantee, contractor and loan administration will be expected to take appropriate action with respect to any specific information which comes to its attention in a prudent management of its daily affairs and which raises a doubt as to the eligibility under Section 907 of employees or beneficiaries of services, assistance, or payments.

Such appropriate action shall include notifying affiliates, sub-contractors, and others with whom agreements or other arrangements are in effect for carrying out the respective grant, contract, or loan activities, of this provision and informing them of their responsibilities under this provision.

In the absence of specific information to the contrary, continued eligibility for payments, assistance, and services may be presumed. Upon receipt of such specific information, grantees, contractors or loan administrators will be expected to give fair notice to the affected individual of a proposed cessation of payments, assistance or services and an opportunity to respond to the proposed termination of payments on such matters as questions of accuracy of identification or whether conviction was for an activity prohibited by Section 907.

Any payment made for services rendered or for benefits provided in contravention of the foregoing, which were rendered or provided after receipt of the specific information referred to above, will be disallowed as a chargeable expenditure of grant, contract, or loan funds.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
800 NORTH QUINCY STREET
ARLINGTON, VIRGINIA 22203

BUREAU OF HEALTH MANPOWER

REFER TO:

APR 26 1968

TO: Bureau of Health Manpower Grantees

FROM: Director
Bureau of Health Manpower

SUBJECT: Disadvantaged Youth Program

The President's Council on Youth Opportunity, chaired by Vice President Humphrey, is marshalling all available resources of the Federal Government to expand the opportunities for growth and guidance for the 16- to 22-year old disadvantaged youth. A similar effort is being urged with respect to the resources of States and counties, private enterprise, and academic institutions. Although the original focus was, and the immediate emphasis is, on summer projects, the President's Council is now urging year-round, long-range efforts to train and to employ our disadvantaged youth.

Those in impoverished condition need special help. They must be trained with skills for which there are now, and will continue to be, a demand. A number of such opportunities exist in the field of health.

In order to obtain maximum utilization of the limited supply of professional health personnel we must, wherever possible, develop supportive personnel trained on the job and in our educational system to perform the many tasks that can appropriately be delegated and carried out under the supervision of physicians, nurses, engineers, and other health specialists.

I urge you to participate actively in this effort and to stimulate other health professionals to do likewise. I urge that a special effort be made to identify and develop the maximum possible number of such opportunities for training and employment during the summer of 1968, and on a continuing basis. I urge you to explore the availability of financial support for this purpose from existing resources, and from any additional available sources in cooperation with State and local youth opportunity programs. However, in employing disadvantaged youth with funds from Bureau of Health Manpower grants already awarded to your school, please remember that their work must be in accordance with the purpose for which the grant was originally made.

Please provide a report on any action taken at your school for assisting disadvantaged youth which utilized Bureau of Health Manpower grant funds. Send the report to the Disadvantaged Youth Employment Coordinator, Bureau of Health Manpower, BCT #1, Room 802, 800 North Quincy Street, Arlington, Virginia 22203.

TO: Deans, Directors and Department Chairmen
Vice Chancellors
Budget and Business Offices

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD. 20014
AREA CODE 301 TEL: 656-4000

MAR 4 1968

TO : Public Health Service Grantees

FROM : Chief, Special Research Resources Branch, Division of Research Facilities and Resources, NIH

SUBJECT: Restrictions on International Travel

Current restrictions on international travel by the Department of Health, Education, and Welfare are described in the attached memorandum of the Chief, Division of Grants Administration Policy, DHEW. The Public Health Service finds it necessary therefore to withdraw all authority previously granted for use of grant funds for all foreign travel, including Canada, to be commenced on or after March 11, 1968. This withdrawal of authority applies also to the grantee institutions included in the Public Health Service Prior Approval Program.

Where the principal investigator or program director believes that the foreign travel planned is urgently required for the successful prosecution of the project, a request for reconsideration with special justification may be submitted for review. Such requests should be submitted through this office. For any foreign travel subsequently approved, however, U. S. flag carriers must be used (1) for departure from or entry into the United States and (2) for any other portions of the trip where U. S. carriers are available.

Because of the necessity for immediate action, this notice is being mailed in bulk. As a consequence some individuals may receive more than a single copy. It is with regret that we take this rather drastic action and we sincerely hope that you will understand the situation.

Bruce D. Waxman

Attachment

Note: This holds for all components of H.E.W.

3/7/68 WHP

February 23, 1968

Director
Division of Allied Health Manpower
U.S. Public Health Service
800 North Quincy Street
Arlington, Virginia 22203

Dear Sir:

Please send me a copy of the Report of the Third National Conference on Public Health Training (Public Health Service Publication No. 1728) as per your release dated February 5, 1968 (HEW-T13).

Thank you!

Sincerely,

Robert E. Shank, M. D.
Danforth Professor of
Preventive Medicine
Head of the Department

KRESS 557-6388

(Home) 363-7227

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
Bureau of Health Manpower
Arlington, Virginia 22203

FOR RELEASE IN A.M. PAPERS HEW-T13
Monday, February 5, 1968

The Report of the Third National Conference on Public Health Training has been released, Surgeon General William H. Stewart, of the U.S. Public Health Service (PHS), announced today. The Conference was held August 16-18, 1967, in Washington, D.C.

The Report's twelve recommendations reflect the health issues outlined in the remarks of Dr. Leonard D. Fenninger, Director of the PHS Bureau of Health Manpower, at the opening of the Conference, and those pointed out by the Conference Chairman, George James, M.D., Dean, Mount Sinai Hospital School of Medicine, in a letter to Dr. Stewart.

Dr. Fenninger told the conferees that "the restoration of our environment and the provision of all types of health services, community and individual, are among the most significant issues that our society faces today . . . Our resources, particularly people who are prepared to plan and deliver valuable services, to teach others, and to develop new ideas, are in very short supply." Commenting on the specific situation in the public health field, Dr. James noted that the emphasis on public health programs is shifting and that the shift has "challenged our academic and service institutions to initiate the diversified training programs necessary to meet the needs."

The Conference's recommendations focus on training mechanisms designed to provide more and better qualified people to fill health and health-

(MORE)

related manpower gaps. They call for increases in student assistance programs, motivational programs designed to help alleviate faculty shortages, expansion of basic support of institutional training programs, extension of public health training support to qualified institutions and health disciplines not now being so supported, and a variety of other programs and projects especially intended to improve the quality and increase the quantity of manpower in the broad field of public health.

Copies of the Report of the Third National Conference on Public Health Training (Public Health Service Publication No. 1728) are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402, at 40 cents a copy. Single copies may be obtained from the Director, Division of Allied Health Manpower, U.S. Public Health Service, 800 North Quincy Street, Arlington, Virginia 22203.

# # #

PUBLIC INFO—[illegible]
(Home)—[illegible]

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20014

FOR RELEASE IN A.M. PAPERS — NIH-099
Wednesday, January 17, 1968

The National Advisory Cancer Council released today its annual public report on the state of the art in cancer research.

"Progress Against Cancer, 1967" deals largely with research on viruses as cancer-causing agents in laboratory animals and the efforts being made to identify viruses that may give rise to malignant diseases in man. Progress in other areas of cancer research is also described.

The Council, established by the National Cancer Institute Act of 1937, advises the Surgeon General of the Public Health Service on general policies, programs and needs, and reviews research developments and their application to the cancer problem. Its first published report, "Progress Against Cancer, 1966" was issued a year ago under the Council's authority to collect information on cancer research and make it available to health agencies, physicians, research scientists and the general public.

The 65-page current report emphasizes that no virus has been identified as the causative agent in any form of human cancer. However, since viruses are known to cause a variety of cancers in lower animals, many scientists believe they are also one of the causes of cancer in man. With this as a working hypothesis, investigators are pursuing two many lines of research, including the development of an immunizing technique or agent, such as a vaccine, that could prevent virus-caused malignant disease.

(more)

"Progress Against Cancer, 1977" is fully illustrated and includes a complete bibliography on cancer-cause research. Issued as Public Health Service Publication No. 1730, it can be purchased from the Superintendent of Documents, U. S. Government Printing Office, Washington, D.C. 20402. The price is 40 cents per copy.

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NOTE TO CORRESPONDENTS:

Copies of the report are available from the Research Information Branch, National Cancer Institute, Bethesda, Maryland 20014 (Phone 301-496-5541).

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

Instructions for Preparing Application for Research Grant—Continuation Support

General Information: The enclosed forms must be completed and returned by the date shown on the attached record so that your application for the next budget period of your project period grant can be processed.

Forward the following completed forms in the enclosed preaddressed envelope:

1. The signed original and first six carbon copies of Form PHS 2590–1. *Do not separate the sets or remove the carbons.*
2. Annual invention statement (Form PHS–3945).
3. Acknowledgment post card.
4. Notice of Research Project.

Instructions: Form PHS–2590–1 (Rev. 7–65) consists of Sections I, II, III, and IV. Complete each section. Fiscal information provided should be verified by the fiscal officer and/or official who is authorized to sign for your organization. Please forward the instructions along with the completed form to the responsible administrative authority within your organization.

Section I—Instructions for Page 1

Items for which no instructions are provided are self-explanatory.

2. Dates of Entire Approved Project Period. Insert the dates of the total project period as approved by the Public Health Service and shown on your Notice of Research Grant Awarded.

3. Dates of Next Budget Period. Insert the dates of the period covered by the budget (p. 2.)

4. Amount Requested for Next Budget Period—Direct Costs Only. The Public Health Service will calculate the indirect cost and include that amount in the award.

5.D. Area Code and Telephone No.(s). List the telephone No.(s) where the Principal Investigator may generally be reached.

11. Identify Organizational Component Responsible for Conduct of Scientific Aspects of Project. For this item the applicant organization must either list itself again or identify that major organizational component or affiliated unit which has the responsibility for assuring a proper environment for the conduct of the scientific aspects of the project (as against legal responsibility for use of the funds). The component listed in item 11 will receive credit for the research project award in applications made for PHS General Research Support and Biomedical Sciences Support Grants, subject to the general policies governing these grants. Failure to complete item 11 may result in forfeiture of such credit.

Item 11 *must* be completed even when it is identical with item 8. For example, if the applicant organization in item 8 is a hospital, research institute, or a separate health professional school, items 8 and 11 usually will be identical.

Where the applicant in item 8 is a state health department, university, or foundation affiliated with a university, particular care should be exercised in completing item 11. A state health department should indicate the major division, hospital or laboratory whenever appropriate. A university must list the particular school involved (e.g., school of engineering, school of medicine). In cases where an affiliated organization is involved, such as a university with affiliated hospitals or a foundation affiliated with a university, the applicant may name an affiliate organization in item 11 *provided:* (1) the work undertaken in connection with the research project will be conducted primarily on the premises of the affiliated organization; and (2) the applicant organiza-

tion follows a *consistent policy* of similarly identifying the appropriate affiliated organization *on every PHS research project grant application* when the research is or will be conducted on the premises of such an affiliate.

14. Established Indirect Cost Rate. Enter the current indirect cost rate negotiated with the Public Health Service. If your institution has not developed an indirect cost rate proposal, such a proposal should be submitted *directly to the Financial Management Branch, National Institutes of Health, Bethesda, Md., 20014.*

16. Signatures. This form requires the signature of both the principal investigator and that of the official authorized to sign for the applicant organization.

Section II—Budget

On page 2 itemize, by budget categories, your TOTAL estimated needs (for direct costs) for the next budget period. Your budget request should represent a reappraisal of your total needs for the coming period. The general level of support recommended by the council will be the guide for both grantees and awarding institutes and divisions in requesting and determining annual awards, but actual amounts awarded will be determined by anticipated needs, funds remaining from awards previously made to support the project, and availability of congressional appropriations.

Use page 3 and continuation pages as necessary for itemization and/or justification. Space provided in Item C, page 3 should be used to explain *any* increase or decrease in the amount previously recommended.

If you require guidance in preparing your Application for Research Grant Continuation Support, contact the awarding Institute or Division sponsoring your project period grant.

Section II.A.—Direct Costs

Personnel. List all positions—professional, technical, secretarial, clerical, and others whether or not salary is requested. Identify each key professional by name, if known, or by expected qualifications if not yet employed. Indicate percent of time or effort on project for each professional. Indicate hours per week on the project for each nonprofessional.

Fringe benefits, if treated consistently by the grantee institution as a direct cost to all sponsors, may be requested separately for each individual in proportion to the salary requested, or may be entered as a total if your institution has established a composite fringe benefit rate.

Consultant Services. Name each consultant and his affiliation, if known, and indicate the nature of the consultant service to be performed. Indicate expected rate and total consultant fees, travel, per diem and related costs for each consultant.

Equipment. List all items of equipment requested and the cost of each item. Identify any item requested in an earlier application but not yet purchased and any item which duplicates equipment already available. Provide justification for present need.

Supplies. List by major types, with related amounts.

Travel:

A. Domestic—List number of trips and total cost.

B. Foreign—List destination and costs. Justify and describe on page 3.

Hospitalization. Indicate the number of patient days and the cost per day or other basis used to support the computation. Provide data used in arriving at outpatient costs, including travel and payment to subjects, if any. State the date of the standard hospitalization rate agreement that your institution has negotiated with the Public Health Service. Indicate any exceptions requested and justify. In the absence of a standard rate agreement, use provisional rate proposals and request that a standard rate agreement be negotiated.

Alterations and Renovations. Identify proposed changes and provide justification on page 3.

Publication Costs. Include items such as page costs, photographs, monographs, books, symposia papers, reprints, etc.

All Other Expenses. List all other necessary expenses by major categories such as repair costs, communication costs, etc. Include rentals, leases, and contract services.

Section II.B., C., and D

Brief explanatory statements are all that are necessary; however, it is hoped you will make use of this additional space to supply all necessary supplemental information regarding your proposed budget.

Instructions for Section III Fiscal Data for Current Budget Period

Fiscal Data for Current Budget Period

Column 1. Enter in column 1 the itemized budget approved by the PHS for the current year as evidenced by the notice of award. If changes in the budget have been approved by the PHS since the notice of award was issued, enter the latest approved figures.

Column 2. Insert the date at the top of the column through which actual expenditure data are available. Enter actual expenditures incurred from the beginning date of the current budget period through the date indicated.

Column 3. Entries should reflect your best estimate of expenses and obligations by category totals that will be incurred in the remainder of the current budget period.

Column 4. Total estimated obligations and expenditures entered should cover the entire current budget period.

Column 5. Subtract Column 4 from Column 1 to arrive at estimated unobligated balance at end of current budget period.

Section IV Summary Progress Report

FOR PROPOSALS INVOLVING HUMAN SUBJECTS, INCLUDING CLINICAL RESEARCH, SEE SPECIAL INSTRUCTIONS FOR PUBLIC HEALTH SERVICE APPLICATIONS INVOLVING HUMAN SUBJECTS. Follow instructions for remaining items.

The signed original and the first six carbon copies of Form PHS–2590–1 (Rev. 7–65) are to be returned. The three remaining copies are intended for: the principal investigator, the business office, and the research office involved, or such other distribution as may be needed within your institution.

ROLLINS--521-5600
Ext.6125

Home--933-1649

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
Division of Medical Care Administration
800 North Quincy Street
Arlington, Virginia 22203

FOR RELEASE IN P.M. PAPERS **HEW-S72**
Thursday, December 14, 1967

Surgeon General William H. Stewart announced today that the second in a series of examinations will be offered across the Nation on January 11 and 12, 1968, to directors of independent laboratories who do not meet the educational and experience requirements for providing services in the Medicare program.

The written examinations are open to those directors who failed to achieve a satisfactory grade in one or more parts of the 1967 examination as well as to directors who wish to take the examination for the first time. At present, 2,527 of the more than 2,700 independent laboratories surveyed for the Medicare program are certified.

The test for laboratory directors, sponsored by the Public Health Service, will be administered in most instances by the State agencies which recommend certification of providers of service under Medicare. There is no charge for the examination.

It has been estimated that one-half billion clinical diagnostic tests are performed annually in the United States. In most States there are no regulations controlling the employment standards and performance of

(More)

clinical laboratories. The examinations have been designed to assure that independent clinical laboratories certified for participation in Medicare are directed by qualified persons.

Developed under a Public Health Service contract by the Professional Examination Service of the American Public Health Association with the assistance of a select advisory committee of clinical laboratory experts, the examination will include a general section covering administration, organization, equipment, facilities, safety, ethics, records, and quality control, plus separate sections in five laboratory specialties. Laboratory directors having degrees and pertinent experience in one of the specialties may qualify for supervision of other of the specialties by achieving a satisfactory grade in the appropriate examination.

Dr. Stewart noted that only 70 directors of the 457 taking the examination last June failed to qualify their laboratories for coverage under Medicare.

# # #

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL
COMMUNICABLE DISEASE CENTER
ATLANTA, GEORGIA 30333
TELEPHONE: (404) 633-3311

October 17, 1967

Robert Shank, M.D.
Chairman, Department of Preventive Medicine
Washington University School of Medicine
660 South Euclid
St. Louis, Missouri 63110

Dear Dr. Shank:

I trust that you already know (as a result of my telegram of October 16) that the Conference for Medical Educators scheduled for November 15, 16 and 17 has been postponed.

During the early months of each new fiscal year it is usually possible to determine the kind of fiscal support which will be provided for our program. As you are aware, fiscal expectations which were reasonable earlier in the year, and which permitted us to plan the medical educators' program, have not been fulfilled. Therefore, we have postponed this meeting.

I am entirely aware that this change in our plans may cause you real inconvenience - schedule changes, lost time, and so on. I want to apologize for that because I understand the difficulty of adding to, and later cancelling from, a schedule already critically full.

Despite this operational "flat tire" I hope you will plan to meet with us when our fiscal affairs permit the rescheduling of this program.

Sincerely yours,

David J. Sencer

David J. Sencer, M.D.
Assistant Surgeon General
Director, National Communicable
Disease Center

APPLICATION FOR REGISTRATION

I will ___ I will not ___ attend the Conference for Medical Educators to be held at the National Communicable Disease Center, Atlanta, Georgia from November 15 through November 17, 1967.

NAME (please print): _____

ADDRESS: _____

DATE: _____ SIGNED: _____

MODE OF TRANSPORTATION: AIR ___ AUTO ___ RAIL ___

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
BUREAU OF DISEASE PREVENTION AND ENVIRONMENTAL CONTROL
NATIONAL
COMMUNICABLE DISEASE CENTER
ATLANTA, GEORGIA 30333

OFFICIAL BUSINESS

POSTAGE AND FEES PAID
U. S. DEPARTMENT OF H. E. W.

National Communicable Disease Center
Atlanta, Georgia 30333

Attn: Seth N. Leibler, Ed. D.
Chief, Training Unit
Tuberculosis Program

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL
COMMUNICABLE DISEASE CENTER
ATLANTA, GEORGIA 30333
TELEPHONE: (404) 633-3311

October 3, 1967

Robert Shank, M.D.
Chairman, Department of Preventive
Medicine
Washington University
School of Medicine
660 South Euclid
St. Louis, Missouri 63110

Dear Dr. Shank:

I am writing to extend a most cordial invitation for you to attend a conference for medical educators which will take place here at the National Communicable Disease Center from November 15 through 17, 1967. An Ad Hoc Advisory Committee has recommended that you attend the conference because of your special interest in the field of medicine and because of your position in the Washington University School of Medicine.

The purpose of this conference is to apply technological advances in education to the teaching of infectious diseases in the medical school setting. The urgency of such application is apparent to us all. Each day produces new knowledge concerning the prevention and treatment of disease which should be incorporated into medical school education. Yet curricula which are already overextended can hardly be expanded further to meet additional needs. This dilemma can be partially resolved by means of sophisticated educational technology: computer assisted instructional systems, closed circuit live and pre-recorded television, programmed instruction and single concept films.

Our November conference is directed to this problem. It will demonstrate the applicability of educational technology to medical school training using the communicable diseases (tuberculosis more particularly) as an example. I hope you will be able to come -

As to the details:

Your travel and subsistence will be paid by the National Communicable Disease Center.

Additional information concerning travel, lodging, program, etc. will be sent to you as soon as you tell us that you will attend.

Any questions you have about this conference can be answered by

Seth N. Leibler, Ed.D.
Chief, Training Unit
Tuberculosis Program
National Communicable Disease Center
Atlanta, Georgia 30333

Write, or call him collect, area code (404) 633-3311, extension 7777.

Please let us know promptly if you plan to attend. A self-addressed, stamped registration card is enclosed for your convenience.

Sincerely yours,

David J. Sencer

David J. Sencer, M.D.
Assistant Surgeon General
Director, National Communicable
Disease Center

Enclosures (2)

AD HOC ADVISORY COMMITTEE

Robert J. Anderson, M.D.
Medical Director
American Thoracic Society

Oscar J. Balchum, M.D.
Hastings Associate Professor of Medicine
School of Medicine
University of Southern California

William R. Barclay, M.D.
Associate Professor of Medicine
School of Medicine
University of Chicago

John H. Chapman, M.D.
Assistant Dean and Professor of Medicine
Southwestern Medical School
University of Texas

George W. Comstock, M.D.
Associate Professor of Epidemiology
School of Hygiene and Public Health
Johns Hopkins University

Winthrop M. Darney, M.D.
Professor of Internal Medicine
Medical Chest Section
University of Michigan

Robert Green, M.D.
Associate Professor of Medicine
University of Michigan

William Gaenor, M.D.
Chief, Chest Diseases
National Jewish Hospital

Ross McLean, M.D.
Associate Professor of Medicine
Emory University

Gordon Wanek, M.D.
Director, Medical Education
American Thoracic Society

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RECEIVED
PUBLIC BUILDINGS SERVICE
Oct 16 4 11 PM '67
COMMUNICATIONS OFFICE
ST. LOUIS, MO.

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HWCD

FM DAVID J SENCER MD DIR CDC ATLANTA GA

TO M KENTON KING MD DEAN WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

/NITE LTR/660 SOUTH EUCLID ST LOUIS MO

BT

REGRET THAT MEDICAL EDUCATORS CONFERENCE SCHEDULED FOR NOVEMBER 15,

16, 17 MUST BE CANCELLED. PLEASE NOTIFY:

Middelkamp

NEAL MIDDLEBROOKS, M.D.

CARL V. MOORE, M.D.

ARNOLD GOLDMAN, M.D.

CARL G. HARFORD, M.D.

ROBART SHANK, M.D.

JOHN A. PIERCE, M.D.

LETTER FOLLOWS. - 10/27/67

BT Revised list received, accept

CONFIRMATION COPY

This is a confirmation copy of a message telephoned

to [illegible] at [illegible] M.

on 10/16/67

General Services Administration

Public Buildings Service

Main 1-8100 Sta 743

Telephoned by [illegible]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
9000 ROCKVILLE PIKE
BETHESDA, MD. 20014

July 28, 1967

To : Public Health Service Fellowships and Training Grant Coordinators and Business Officers, Grantee Institutions

From : Director, Office of Extramural Programs
Office of the Surgeon General, PHS

Subject: Clarification of Public Health Service Policy on:
(1) Teaching by and Supplementation of PHS Fellows and Trainees
(2) Special Stipends for PHS Trainees

Since there have been numerous inquiries by Public Health Service grantees and staff with regard to the PHS position on the above subjects, the following additional information is provided to clarify these issues:

1. Teaching and Supplementation

The PHS recognizes the close interrelationship between teaching and research in the academic environment and therefore encourages its fellows and trainees to undertake teaching experiences that contribute meaningfully to their academic training. Two conditions, however, should be observed. First, any such teaching experience undertaken by a PHS fellow or trainee should not significantly prolong the time required for the accomplishment of the training objective for which the award is made. Second, the newly established PHS policy on supplementation is applicable to the provision of funds by grantee institutions to PHS fellows and trainees as reimbursement for teaching as well as other services that may be rendered. This policy is as follows:

A. PHS Postdoctoral Fellows and Trainees

PHS postdoctoral fellows and trainees are expected to devote their entire professional effort to the achievement of their training objectives. Unless otherwise indicated by the PHS awarding unit, grantee institutions may not provide funds to postdoctoral fellows or trainees for any reason, including employment involving teaching or other responsibilities, where the combination of such funds and the PHS stipend exceeds the established postdoctoral stipend levels or ceilings. Loans are excluded from this general prohibition.

B. PHS Predoctoral Fellows and Trainees

PHS predoctoral fellows and trainees are expected to devote their entire professional effort to the achievement of their training objectives. Supplementation (defined as the provision of funds by the grantee institution to a PHS fellow or trainee in addition to his stipend in a combination which then exceeds established PHS stipend levels or ceilings) is permitted only if all of the following condition are observed:

1. No services are to be required of the fellow or trainee in order to receive supplemental funds.
2. The source of funds for supplementation must be non-Federal, expect that Public Health Service General Research Support or Biomedical Sciences Support grants may be used for this purpose.

3. The decision to supplement the stipend of a predoctoral fellow or trainee must be made at the institution level, rather than at any lower level. Records indicating names, amounts, dates and reasons for supplementation must be maintained by the institution and made available upon request from the awarding unit.

Under no circumstances may supplementation be used as an inducement for purposes of recruitment.

No more than $1,000 per 12-month period (prorated for shorter periods) may be provided as supplementation without prior Public Health Service approval.

The word "services" in item #1 includes teaching services. Under this restriction, therefore, PHS predoctoral fellows and trainees may not be reimbursed by the grantee institution for their teaching efforts even if these efforts are directly related to their training objectives. Supplementation cannot be provided to a PHS predoctoral fellow or trainee as payment for any service, including teaching.

2. "Special" Stipends for Trainees

The language pertaining to special stipends as contained in the current (July 1, 1967) PHS Policy Statement on Grants for Training Projects reads as follows: "The amounts for special stipends (including allowances) are to be determined on an individual basis between the program director and the awarding unit." This statement is insufficient to clarify the common misconception that the third postdoctoral stipend step of $7000 represents the maximum stipend which may be paid to a trainee regardless of his relevant postdoctoral experience.

Trainees with three or more years of relevant postdoctoral experience may be paid stipends in excess of $7000 per year if they are designated as "special trainees." In such instances, it is not intended that prior negotiations must always be undertaken on an individual trainee basis between the training program director and the awarding Institute or Division. Some awarding units of the PHS have provided their training program directors with guidelines appropriate for their training programs dealing with stipend levels for trainees with three or more years of relevant postdoctoral experience. In the absence of appropriate guidelines governing "special trainees," negotiations on an individual trainee basis with the PHS awarding unit are necessary before stipends in excess of $7000 per year can be paid.

Information concerning policy applicable to residency and post-residency programs must be obtained from the awarding Institute or Division of the Public Health Service.

Ernest M. Allen

Ernest M. Allen, Sc.D.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL
COMMUNICABLE DISEASE CENTER
ATLANTA, GEORGIA 30333

TELEPHONE: (404) 633-3311

June 9, 1967

Dear Doctor:

Your name currently appears on our mailing list to receive film release announcements, film guides, and other audiovisual publications relating to preventive medicine and public health.

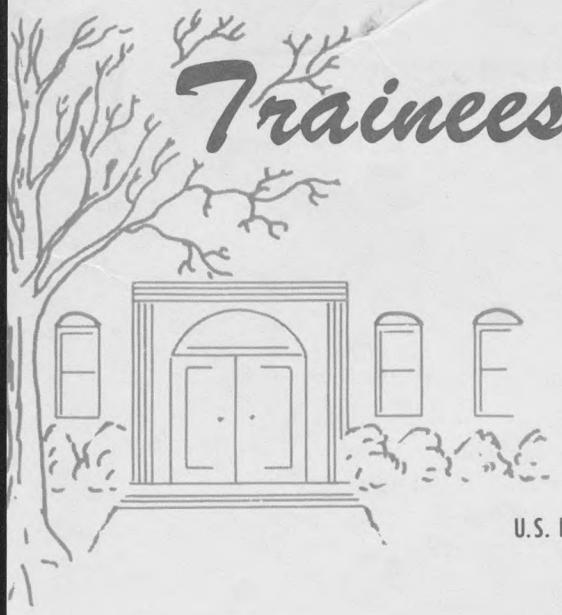
Will you kindly assist us in up-dating this mailing list by completing the form below and returning it to us as soon as possible? A return addressed envelope is enclosed.

Sincerely yours,

mailed 6/21/67

Frances A. Bourn
Staff Assistant (Inquiry)
Office of the Director
Public Health Service Audiovisual Facility

pet to go if you are still interested in receiving these



Traineeships

for PROFESSIONAL HEALTH PERSONNEL under the Public Health Traineeship Program

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

FINANCIAL LEVEL OF AWARDS

- Stipend—determined by the type of traineeship and the number of dependents

Type of Traineeship		*Yearly Ceiling**
Postdoctoral		
Requirements: Doctoral degree—Acceptance for graduate study	With no postdoctoral training	$6,000
	With 1-year postdoctoral training	6,500
	With 2-year postdoctoral training	7,000
Postbachelor		
Requirements: Bachelor degree—Acceptance for graduate study	1st year	3,000
	2d year	3,300
	3d year	3,600
	All years	2,400
Prebachelor		
Requirements: Professional licensure in nursing or dental hygiene—Acceptance for baccalaureate training		

*Plus $500 per year for each dependent.

- Tuition and Fees—standard charges of the school
- Transportation—to the school, once, at .08 cents per mile

‡These benefits may not be supplemented from any other Federal educational assistance program.

For further information and application blanks write to:

Health Manpower Grants Branch
Division of Health Manpower Educational Services
Bureau of Health Manpower
Public Health Service
U.S. Department of Health, Education, and Welfare
Arlington, Va. 22203

DISCRIMINATION PROHIBITED—Title VI of the Civil Rights Act of 1964 states: "No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance." Therefore, the Public Health Traineeship Program, like every program or activity receiving financial assistance from the Department of Health, Education, and Welfare, must be operated in compliance with the law.

Public Health Service Publication No. 1147
Revised June 1967

THE PUBLIC HEALTH TRAINEESHIP PROGRAM

[illegible]

PURPOSES

- to increase the number of trained professional public health personnel
- to bring new people into the field of public health through training

WHO MAY APPLY

- individuals who have completed their basic professional education and whose skills are needed in modern public health practice such as:

physicians	health educators	veterinarians
nurses	dentists	medical social workers
engineers	dietitians	nutritionists
sanitarians	laboratory personnel	and others

ELIGIBILITY REQUIREMENTS

- completion of basic professional education
- U.S. citizenship—(or admitted to the United States for permanent residence)
- intent to enter—or remain in—public health employment
- prior acceptance by the school of your choice that offers a nationally recognized or specialized public health training program in your professional field

LENGTH OF TRAINING

- traineeships may not exceed a period of 12 months
- additional awards may be made to support programs of study of several years' duration

HOW TO APPLY

- directly to a school having a grant from the Public Health Service with which to award traineeships
- to the Public Health Service, through the school of your choice, when enrolled in a school which does not have a traineeship grant

WHEN TO APPLY

- generally between January 1 and March 1—for training to begin in the fall

SPECIAL NOTE FOR NURSES

- public health nursing traineeships are awarded only through schools of nursing nationally approved to prepare graduate nurses for first level positions in public health. Requirements and application procedures are described in *Traineeships for Registered Nurses Under the Public Health Traineeship Program*. Copies may be obtained by contacting the Health Manpower Grants Branch.

A NOTE FOR RESIDENTS

- a separate document, *Residency Training in Preventive Medicine and Dental Public Health*, describes the program supporting residency training in general preventive medicine and preventive medicine—public health for physicians and residency training in dental public health for dentists. Copies may be obtained from the Health Manpower Grants Branch.

[illegible]

May 16, 1967

U.S. Department of Health,
Education and Welfare
Public Health Service
Bureau of Disease Prevention
and Environmental Control
National Communicable Disease Center
Atlanta, Georgia 30333

Gentlemen:

Thank you for the invitations to attend the dedication and demonstration of The Community Medical Television System in Atlanta on May 27. Dr. Robert E. Shank has returned the card advising that he will be unable to attend however.

My reason for writing is that we received three invitations, one addressed to Dr. Shank and the other two to the Chairman of the Department of Preventive Medicine, which position Dr. Shank holds. Therefore you may want to remove these two stencils from your mailing lists.

Sincerely,

(Mrs.) Dorothy C. Olenyik
Secretary to Dr. Shank

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
9000 ROCKVILLE PIKE
BETHESDA, MD. 20014

January 24, 1967

TO : Heads of Institutions Receiving Public Health Service Grants

FROM : Director, Office of Extramural Programs, OSG

SUBJECT: Institutional assurances relating to investigations involving human subjects

On July 1, 1966, Dr. William H. Stewart, Surgeon General, Public Health Service, issued PPO #129, Revised; Subject: Revised procedure on clinical research and investigation involving human subjects. Among the procedural revisions was the statement, on page 4, that each application including or likely to include investigations involving human subjects, including clinical research, must refer to the institution's assurance as follows:

> "The investigations encompassed by this application have been or will be approved by the committee of associates of the investigator(s) in accordance with this institution's assurance on clinical research dated_____."

Since the normal processing of each application routinely includes the verification of this acceptance, the application itself no longer needs to include this reference. Accordingly, printed on the reverse side of this memorandum is a revised page 4 to the July 1, 1966 document. The revised page 4 deletes the first two paragraphs of page 4, PPO #129, Revised, July 1, 1966, and eliminates the reference to the interim procedure which is no longer effective.

Ernest M. Allen

Ernest M. Allen, Sc.D.

(over)

(To be substituted for page 4, PPO #129, Revised, July 1, 1966)

4

No new, supplemental, renewal, or continuation application for a Public Health Service grant or award to support investigations involving human subjects will be accepted for review unless the PHS has approved an institution-wide assurance.

Nothing in the institution-wide assurance should inhibit PHS staff, advisory groups, or consultants from (1) identifying concern for the welfare of human subjects, and communicating this concern to the grantee institution, or (2) recommending disapproval of the application if the gravity of the hazards and risks so indicate.

In the case of awards to U.S. citizens receiving fellowships for training abroad, special conditions or circumstances relating to the place at which the training is being provided may upon occasion justify modification of these requirements. Requests from the sponsor for approval of such modifications must be reviewed by the Office of International Research, NIH, and approved by the PHS Bureau chief concerned.

ORIGINATING OFFICE: Office of the Surgeon General, PHS

APPROVED BY: Director, Office of Extramural Programs, OSG

Ernest M. Allen

Date: 1/24/67

Index: Clinical Research
Human Subjects, Investigations Involving
Individuals, Rights and Welfare of

MEMBERS OF PUBLIC HEALTH SERVICE PUBLIC ADVISORY GROUPS
JANUARY 1, 1967
WASHINGTON UNIVERSITY PERSONNEL

I. Bureau of Disease Prevention and Environmental Control

A. National Center for Chronic Disease Control

1. Cancer Control Program Advisory Committee

Scott, Wendell G.		1970	Radiology

B. National Center for Urban and Industrial Health

1. Accident Prevention Advisory Committee

Hoekstra, Lilly D.		1968	Hospital Administration

II. National Institutes of Health

A. National Institute of Arthritus and Metabolic Diseases

1. Board of Scientific Counselors, NIAMD

Daughaday, William H.		1967	Medicine

B. National Cancer Institute

1. Cancer Chemotherapy Collaborative Clinical Trials Review Committee

Loeb, Virgil, Jr.	Chairman	1969	Medicine

C. National Institute of General Medical Sciences

1. National Advisory General Medical Sciences Council

Lowry, Oliver H.		1968	Pharmacology

2. Behavioral Sciences Training Committee

Bunch, Marion E.		1969	Psychology

3. Biophysical Sciences Training Committee

Tolmach, Leonard J.		1968	Radiology

4. Research Career Award Committee

Enders, Allen C.		1967	Anatomy

D. National Heart Institute

1. Heart Program - Project A Committee

Smith, John R.		1970	Medicine

2. Heart Training B Committee

Wessler, Stanford		1968	Medicine

3. Thrombolytic Agents Committee

Sherry, Sol	Chairman	1968	Medicine

E. National Institute of Neurological Diseases and Blindness

1. National Advisory Neurological Diseases and Blindness Council

Becker, Bernard	1967	Ophthalmology

2. Board of Scientific Counselors, NINDB

Schwartz, Henry G.	1968	Neurosurgery

3. Communicative Disorder Research Training Committee

Ogura, Joseph H.	1968	Otolaryngology

4. Neurological Science Research Training A Committee

Landau, William M.	1967	Neurology

5. Neurological Science Research Training B Committee

McDougal, David B., Jr.	1967	Pharmacology

6. Neurology Program - Project A Committee

O'Leary, James L.	Chairman	1967	Neurology

7. Vision Research Training Committee

Gay, Andrew J., Jr.	1969	Ophthalmology & Neurology

F. Division of Research Facilities and Resources

1. National Advisory Research Resources Council

Cox, Jerome R., Jr.	1969	Biomedical Computer Laboratory

G. Division of Research Grants

1. Career Development Review Branch

a. Anatomy and Pathology Fellowships Review Committee

Luse, Sarah A.	1970	Anatomy

2. Research Grants Review Branch

a. Arthritis and Metabolic Diseases Program - Project Committee

Avioli, Louis	1970	Medicine

b. Bacteriology and Mycology A Study Section

Harford, Carl G.	1969	Medicine

c. Biophysics and Biophysical Chemistry B Study Section

Weissman, Samuel I.	1969	Chemistry

d. Cardiovascular A Study Section

Danforth, William H.	1970	Medicine

e. Cell Biology A Study Section

Clark, Sam L., Jr.	1967	Anatomy

f. Communicative Sciences Study Section

Eldredge, Donald H.	1970	Otolaryngology
Smith, Catherine A.	1970	Otolaryngology

g. Endocrinology Study Section
Kipnis, David M. Chairman 1967 Medicine

h. Epidemiology and Disease Control Study Section
Wessen, Albert F. 1967 Sociology & Anthropology

i. General Medicine A Study Section
Bricker, Neal S. Chairman 1968 Medicine

j. Hematology Study Section
Chaplin, Hugh, Jr. 1967 Medicine & Preventive Medicine

k. History of the Life Sciences Study Section
Rosenzweig, Saul 1968 Psychology

l. Human Embryology and Development Study Section
Moog, Florence 1970 Zoology

m. Neurology A Study Section
Taveras, Juan M. 1968 Radiology

n. Neurology B Study Section
Goldring, Sidney 1968 Neurosurgery

o. Nutrition Study Section
Shank, Robert E. Chairman 1968 Preventive Medicine

p. Pathology B Study Section
Lacy, Paul E. Chairman 1967 Pathology

q. Pharmacology and Experimental Therapeutics A Study Section
Demis, D. Joseph 1968 Medicine

r. Radiation Study Section
Ter-Pogossian, M. M. 1969 Radiology & Physiology and Biophysics

s. Visual Sciences Study Section
Cohen, Adolph I. 1970 Ophthalmology

III. National Institute of Mental Health

A. Office of Communications

1. National Clearinghouse for Mental Health Information Advisory Committee
Brodman, Estelle 1968 Medical Library & Anatomy

B. Division of Extramural Research Programs

1. Pharmacology and Chemistry Committee
Robins, Eli 1969 Psychiatry

C. Division of Manpower Training Programs

1. Mental Health Training Committee

a. Experimental and Special Training Subcommittee

Gordon, William E.	1969	Social Work

b. Social Work Subcommittee

Schutz, Margaret L.	1970	Social Work

ACCOMPANYING MATERIAL REVISED

October, 1967

OFFICE OF THE DEAN October 12, 1966

TO: Members of the Faculty

FROM: Dr. M. Kenton King, Dean

SUBJECT: Review of Research on Human Beings
PHS acceptance of our statement of assurance dated Sept. 21, 1966

We are pleased to inform you that the Public Health Service has reviewed and accepted the statement of assurance dated September 21, 1966, submitted by the Washington University School of Medicine, as being in compliance with the requirements contained in PPO#129, revised July 1, 1966, relating to investigations involving human subjects.

Please read all of the accompanying material carefully.

The letter which follows, dated "October, 1966," was necessarily written in advance as a part of the material which was submitted to the PHS in our application. Since the letter was found to be acceptable, it is now distributed to you. Of the five appendices which follow, may I point out that A, C, and E require potential action on your part.

Again I express my regret at the amount of paper work required of the faculty by the various branches of government. The Committee within the Medical School has a very difficult task to carry out, and it is hoped that you will give them your full cooperation.

mkk:j
enclosures

REVISED -- October, 1967

WASHINGTON UNIVERSITY

SCHOOL OF MEDICINE

OFFICE OF THE DEAN

660 SOUTH EUCLID AVENUE
ST. LOUIS, MISSOURI 63110

October, 1966

TO: Members of the Faculty

FROM: Dr. M. Kenton King, Dean

SUBJECT: Significant Research Projects Involving the Use of Human Subjects

Enclosures: Appendices A, B, C, D, and E

Please file this communication for use in case you intend to be the principal investigator on a research project involving human subjects. It amends that of April 11, 1966 and should replace it.

The Executive Faculty has approved a set of guidelines for the conduct of research involving human subjects (see Appendix B) by members of the faculty of the School of Medicine. A Committee for the Review of Institutional Clinical Research Involving Human Beings has been appointed (Drs. Winokur, Chairman, Allen, Reynolds, Ogura, Harford, Wessler, and Dodd).

Each principal investigator, whether his work is supported by a grant or not, will be asked to submit five copies of Appendix C to the Committee Chairman (Dr. Winokur at present). The Committee will act promptly on each proposal, and will send two copies of their action to the Dean's Office, one copy to the Office of the Head of the Department, one copy will be returned to the Principal Investigator, and one (the original) will be retained by the Committee Chairman. Appendix C is to be submitted during the planning stage of the experiment in instances where grants are not involved, and before or within seven days of submission of grant applications to the Dean's Office when supporting funds are being sought for a project.

In part this letter and the new policy described hereon is in response to a letter from the Surgeon General, P.H.S. (Appendix D) which revises their previous policy. Appendix A is a paragraph provided for principal investigators to include within their applications for new or renewal research grants or research training grants as is hereforth required. Review of the project by the Committee is accomplished by the submission of Appendix C as described above.

The Committee and the Executive Faculty have recommended that the guidelines (Appendix B) should serve for all significant institutional research on human beings. Therefore, in order to provide for a mechanism of review, Appendix C is also requested on projects not funded by the P.H.S. Appendix A, of course, would not apply to such projects.

Appendix E, which is also available in the Department, is the Consent Form for Human Investigation adopted by this institution. This form is to be completed on all patients undergoing human investigation and a copy is to be filed by the investigator and made available for review by the Committee when requested.

Finally it is to be noted that the Public Health Service requires assurances from the institution of the manner and mechanisms for carrying out the Surgeon General's policy. To accomplish this it has been necessary to charge the Committee for the Review of Institutional Clinical Research with the following responsibilities:

a) the review and approval of all projects involving research at this institution

b) maintenance of an adequate surveillance to protect the rights and welfare of human subjects in all investigational projects

c) to provide guidance and advice for investigators

d) to deal with changes in protocol or emergent problems of investigators

Investigators are instructed to take the initiative in seeking advice from the Committee and notifying them of any contemplated changes in protocol.

Added in October, 1967

1. Appendix C is to be submitted to the Committee in the case of grant supported research regardless of whether or not it involves human beings as subjects. This is for administrative purposes and enables the Dean's Office to be sure that action has been taken on all grant proposals that propose using humans as subjects. Appendix C in the case of research which does not involve humans must be simply checked in the proper place, signed and submitted.

2. Positive action by the Committee on a proposal is in force for one year. Each year a new Appendix C should be filed. If no change has occurred in the essentials of the research, a simple statement such as "no change in direction" is sufficient. If on the other hand significant changes or unpredicted events in the research have occurred, these should be noted on Appendix C.

3. Any research involving radioactive substances should first be cleared through the Isotope Committee before being sent to the Committee for Review of Research on Human Beings.

Appendix A

The investigations encompassed by this application have been or will be approved by the committee of associates of the investigator(s) in accordance with this institutions's assurance on clinical research dated September 21, 1966.

Appendix B

GUIDELINES FOR THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS AT WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

When an investigator conducts studies on humans, the following principles are considered fundamental to the fulfillment of his ethical responsibilities:

1. The scientific investigator shall be an experienced and competent professional working in an environment which allows the systematic collection of accurate data with high scientific validity.

2. The nature and degree of risk or stress to the human subject must be defined as accurately as possible and the experiment designed to minimize the possible risks to the subject.

3. The investigator must provide in advance for the over-all care of any forseeable adverse reactions of the subject, both during the procedure and following it. This requires the participation of professionals competent to care for the health of humans and the availability of facilities necessary for them to render their services.

4. The decision to utilize a human subject in an experiment should be based on the necessity for observing the unique reactions of the human species. Knowledge of the reactions of suitable animals to the experiment is a prerequisite to making such a decision.

5. The conduct of an experiment utilizing a human subject for the purposes of research is appropriate under the following conditions:

a. The knowledge to be gained is of potential benefit to human health.

b. The subject has sufficient understanding of the nature of the experiment -- its purposes and its probable risks to him -- to allow a reasoned choice on his part as to whether or not he chooses to participate. If because of age or mental state or other circumstances the subject legally cannot make a free and reasoned choice to participate in an experiment, then the investigator is responsible for obtaining written permission from the person, agency and/or court authorized to act for such a subject.

Beyond this, it is the responsibility of the investigator to determine that the subject's choice is truly voluntary and not the result of coercion.

c. The potential medical benefits of the investigation far outweigh the risks involved.

d. Plans for the use of human subjects in experiments have been reviewed by the Committee for the Review of Institutional Clinical Research Involving Human Beings.

REVISED October, 1967 -- Discard Previous Appendix C forms

Appendix C

STATEMENT FOR COMMITTEE FOR THE REVIEW OF
INSTITUTIONAL CLINICAL RESEARCH INVOLVING HUMAN BEINGS,
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

From: Date:

Title of Project:

Research Grant Identification (if any)*:

Does this research involve human beings as subjects? No _____

Yes _____

If answer is "No", sign this form and send it to the Chairman of the Committee.
If answer is "Yes", complete this form and send it to the Chairman of the Committee.

Introduction (Brief summary of proposed investigation as it relates to human research):

Statement: In accordance with the policy of the School of Medicine, assurance is given that the rights and welfare of the human subjects in this investigation and the methods to be employed for securing the informed consent of the subjects will be carried out in conformance with the guidelines adopted by the School of Medicine. The following are the risks and potential medical benefits of this investigation.

_____
(Principal Investigator)

Use additional pages if necessary and submit five copies to the Committee Chairman.
*Attach copy of research plan as it appears in grant application

Action of Committee

APPENDIX D

U. S. Public Health Service
Division of Research Grants
Bethesda, Maryland 20014

PPO #129, Revised
POLICY
July 1, 1966

SUBJECT : Investigations Involving Human Subjects, including Clinical Research: Requirements for Review to Insure the Rights and Welfare of Individuals

APPLICABILITY : All Public Health Service Grants and Awards.

EFFECTIVE DATE: Immediately

SUPERSEDES : PPO #129, February 8, 1966
PPO #129 Supplement, April 7, 1966

I. BACKGROUND:

Culminating several years of study by various Public Health Service staff and advisory groups, the National Advisory Health Council passed the following resolution on December 3, 1965:

> "Be it resolved that the National Advisory Health Council believes that Public Health Service support of clinical research and investigation involving human beings should be provided only if the judgment of the investigator is subject to prior review by his institutional associates to assure an independent determination of the protection of the rights and welfare of the individual or individuals involved, of the appropriateness of the methods used to secure informed consent, and of the risks and potential medical benefits of the investigation."

II. POLICY:

The Surgeon General accepted the resolution of the National Advisory Health Council and promulgated the following policy statement on February 8, 1966:

> "No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination: (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of the associates who will provide the review shall be included in the application."

III. REVISED POLICY:

By decision of the Surgeon General, the application of this policy has been extended to all grants and awards of the Public Health Service in the support of research, training, or demonstration projects, including the projects supported through general research support and those of fellows and trainees. The policy is not applicable to grants in support of construction, alterations, renovations, or research resources -- it is obviously applicable to the PHS projects using these facilities and resources.

This policy will be included in all pertinent grant program policy and instruction statements, and will be among the conditions of award agreed upon by grantee institutions and the Public Health Service. The policy applies to all investigations involving human subjects, including clinical research.

A. Assignment of Responsibility

Safeguarding the rights and welfare of human subjects involved in research support by PHS grants is the responsibility of the institution to which the grant is awarded. The institution must assure the Public Health Service that in the case of investigations and activities supported directly by the PHS, it will provide group review and decision, maintain surveillance, and provide advice for investigators on safeguarding the rights and welfare of human subjects. The institution also has the responsibility to provide whatever professional attention or facilities may be required for the safety and well-being of human subjects. The institution shall be responsible for developing the administrative mechanism for review, surveillance, and advice; however, the PHS requires that, prior to inception of each course of investigation, objective decisions be made on the three points cited in the Surgeon General's policy statement (above) by an appropriate committee of associates of the investigator having no vested interest in the specific project involved. The grantee institution may utilize staff, consultants, or both to carry out the review. Any group responsible for review should possess not only specific scientific competence to comprehend the scientific content of the investigations reviewed, but also other competencies pertinent to the judgments that need to be made.

The grantee is required to make and keep written records of the group reviews and decisions on the use of human subjects and to obtain and keep documentary evidence of informed consent relating to investigations carried out with the assistance of PHS financial support.

B. Timing of Review

While this policy requires that review be conducted prior to the use of human beings as subjects, there are advantages to both the PHS and the grantee in having the review conducted prior to application for PHS support. The PHS encourages the institution to do so, if the review can be accomplished without causing unreasonable delay in the application process and if the application is of the type that normally contains a reviewable scientific protocol.

IV. PROCEDURAL REVISIONS -- ASSURANCES OF APPLICANTS AND GRANTEES:

Upon issuance of this policy statement, the PHS will require necessary assurances from the grantee institutions which sponsor investigations involving human subjects, including clinical research. These assurances will cover both the general principles of safeguarding human rights and welfare in the conduct of research and the specific points of the Surgeon General's policy. The assurance should provide explicit information on the policy and procedure it employs for review and decision on the propriety of plans of research involving human subjects. The descriptions will include the competencies represented in the committees of associates utilized for review, the sources of consultants (if used), the administrative mechanisms by which surveillance is provided for projects involving human subjects -- particularly to deal with changes in protocol or emergent problems of investigations, the means of guidance and advice provided for investigators, and the manner in which the institution will assure itself that the advice of the committee of associates will be followed. Copies of documents of institutional policies on these issues should be attached to the memorandum of assurance. An example of an acceptable assurance is attached.

Assurances can be provided which apply only to individual major components of universities or other large institutions in those instances where assurances covering the total institution are impracticable or inadvisable.

Each assurance and its attachments shall be transmitted to the Public Health Service, in care of the Chief, Division of Research Grants. When the Public Health Service has reviewed and accepted the assurance, the Chief, Division of Research Grants, shall so notify both the responsible official of the grantee institution involved and all Public Health Service extramural research program offices.

Each grantee institution shall report currently any changes in its policies, its procedures, or the competencies represented on its committee of associates.

For each application that includes or is likely to include investigations involving human subjects, including clinical research, the applicant institution should make reference to the certification as follows:

> "The investigations encompassed by this application have been or will be approved by the committee of associates of the investigator(s) in accordance with this institution's assurance on clinical research dated _____."

Until an institution-wide assurance has been accepted by the PHS, the institution can fulfill requirements of this policy for individual studies by submitting an assurance with each application for PHS financial support, stating that prior to inception of investigations, the requirements of section III. A. of this Policy and Procedure Order will be followed. The statement must also describe the composition of the group which will conduct the review.

This interim procedure will be acceptable until November 1, 1966. After that date no new, supplemental, renewal, or continuation application for a Public Health Service grant or award to support investigations involving human subjects will be accepted for review unless the PHS has approved an institution-wide assurance.

Nothing in the institution-wide assurance or in the interim policy procedure used in some cases until November 1, 1966, should inhibit PHS staff, advisory groups, or consultants (1) from identifying concern for the welfare of human subjects, and communicating this concern to the grantee institution, or (2) from recommending disapproval of the application if the gravity of the hazards and risks so indicate.

In the case of awards to U.S. citizens receiving fellowships for training abroad, special conditions or circumstances relating to the place at which the training is being provided may upon occasion justify modification of these requirements. Requests from the sponsor for approval of such modifications must be reviewed by the Office of International Research, NIH, and approved by the PHS bureau chief concerned.

Attachment

ORIGINATING OFFICE: Office of the Surgeon General, PHS

APPROVED BY: Grants Policy Officer, OSG

Ernestine Allen

Date: July 1, 1966

Index: Clinical Research
Human Subjects, Investigations Involving
Individuals, Rights and Welfare of

Example of an Acceptable Assurance

Institutional Assurance on

Investigations Involving Human Subjects,

Including Clinical Research

The (name of institution) agrees with the principles of the Public Health Service policy (identified as Policy and Procedure Order 129 dated July 1, 1966) with regard to investigations involving human subjects, including clinical research. This institution agrees that review independent of the investigator is necessary to safeguard the rights and welfare of human subjects of research investigations and assures the Public Health Service that it will establish and maintain advisory groups competent to review plans of investigation involving human subjects, prior to initiation of investigations, to insure adequate safeguard. Group reviews and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved, (2) the appropriateness of the methods used to obtain informed consent, and (3) the risks and potential medical benefits of the investigations.

The institution also agrees to exercise surveillance of PHS-supported projects using human subjects for changes in protocol which may alter the investigational situation with regard to the criteria cited above. The institution further assures the Public Health Service that it will provide advice and consultation to investigators on matters of employing human subjects in investigation, and also that it will provide whatever professional attention or facilities may be required to safeguard the rights and welfare of human subjects involved in investigation. Records of group review and decision on the use of human subjects and of informed consent will be developed and kept by the institution.

Attached as part of this statement are copies of policy and procedure of this institution with regard to use of human subjects in investigation, as well as a description of the groups utilized to review projects for enforcement of these policies and the manner in which the institution will assure itself that the advice of the committee of associates is followed.

Signature: _____

Title: _____

Date: _____

Attachments

Appendix E

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

Consent Form for Human Investigation*

Date

This is to certify that I _____ hereby agree to participate as a volunteer patient in a program of investigation under the supervision of Dr. _____.

The studies have been defined and fully explained by Dr. _____ and I understand that the studies will involve the following special procedures:

_____

_____

_____

_____

_____

_____

_____

_____ _____

Volunteer's Signature Date

(If verbal, rather than written, consent is obtained, this should be noted above in lieu of the signature of the volunteer.)

I, the undersigned, have defined and fully explained the studies involved to the above volunteer.

_____ _____

*A signed copy of this form is to be filed by the investigator.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
800 North Quincy Street
Arlington, Virginia 22203

BUREAU OF STATE SERVICES

REFER TO: DCHS-TRB(AT)

September 15, 1966

Dear Dr. Shank:

Traineeship grants to support medical, dental, and osteopathic students engaged in preceptor-guided apprenticeship training in public health were made available in fiscal year 1965. The purpose of this program is to:

(1) involve these students in the practical application of the principles of public health and preventive medicine or dentistry as they may be applied in private or public health practice,

(2) contribute to the preparation of future physicians and dentists for their role in community health practice, and

(3) provide an insight into the challenges and potentials of careers in public health practice for physicians and dentists.

A copy of the document "Traineeship Grants for Apprenticeship Training under the Public Health Traineeship Program" was forwarded to your office last year. This document provides information on program terms and conditions and instructions for making application. We wish to remind you that the next deadline for the receipt of applications is October 15, 1966. Proposals received by that date will be reviewed in December and notification of Public Health Service action will be made in December 1966 or early January, 1967. Applications should be submitted directly to this office.

A copy of revised policy governing transportation allowances for trainees under Apprenticeship Training Grants is enclosed for your information.

An additional copy of the document governing this program is not enclosed as our supply is extremely limited. If the document is needed, or you desire further information, please contact the appropriate Public Health Service Regional Office or this office. If necessary, you may call us collect (area code 703) 521-5600, extension 6262 and ask for Mr. Westcott.

Sincerely yours,

Elmer L. Hill

Elmer L. Hill, M.D.
Chief, Training Resources Branch
Division of Community Health Services

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Division of Community Health Services
Training Resources Branch
800 North Quincy Street
Arlington, Virginia 22203

TRAINEESHIP GRANTS FOR APPRENTICESHIP TRAINING UNDER THE PUBLIC HEALTH TRAINEESHIP PROGRAM (Section 306, PHS ACT)

REVISION OF TRAVEL ALLOWANCE POLICY

Effective June 1966, policy governing transportation allowances for trainees under Apprenticeship Training Grants is revised to the following:

Transportation Allowances

An allowance for transportation to the site of training may be provided only once for each appointed trainee. It should be calculated at the rate of eight cents per mile for the distance between the actual point of departure and the location of the institution as shown on standard mileage charts. However, mileage should not be allowed in excess of the distance from either (a) the present address or (b) the permanent address (as shown on the Trainee Appointment Statement) to the location of the training institution, whichever is greater. No allowance should be made for per diem expenses during travel, return travel, travel distances of less than fifty miles, travel of dependents, or shipping charges for personal effects or household goods.

When field training is arranged at a distant site and it is necessary for the trainee to establish a temporary residence, an allowance of eight cents per mile should be paid for the distance between the institution and the field training center site. Eight cents per mile may also be allowed for necessary travel within the field training area. No allowance, however, should be made for commuting from the new place of residence to the field training headquarters office during the period of field training, or for food, lodging, etc., in addition to the regular stipend. An allowance for return travel from the field training site to the training institution may be paid only if such return is necessary for completion of the training program.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH
Bethesda, Md. 20014
Area Code 301 Tel: 656-4000

September 13, 1966

TO : Coordinators of Research and Administrative Officials
Grantee Institutions

FROM : Chief, Division of Research Grants

SUBJECT: Travel Funds for 7th International Biochemical Congress, Tokyo, August 1967

The Public Health Service has decided that funds of individual research or training grants are not to be used to pay travel for scientists to attend the 7th International Biochemical Congress in Tokyo, August 1967. The PHS will, however, provide travel assistance for scientists who have good reason to attend this international Congress through a single grant awarded to the American Society of Biological Chemists.

In accordance with the above-described decision, requests now pending at PHS to have certain budget items in current grants transferred into foreign travel to attend the Congress cannot be honored. On the other hand, firm commitments which have been made to those grantees who have received Institute/Division approval for the requested expenditures will be honored. Requests for travel to attend this Congress should not be included in future applications submitted for PHS support, and no future individual requests to use funds already granted will be approved.

Prior to October 15, 1966*, all requests for travel awards to attend the Congress should be addressed to:

Mr. Robert Harte
Executive Officer
American Society of Biological Chemists
9650 Rockville Pike
Bethesda, Maryland 20014

Inasmuch as time is now very short for such requests, please transmit this information to the research investigators and training program directors in your institution as soon as possible.

Signed Eugene A. Confrey, Ph. D.

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* For PHS grantees, extended from deadline of October 1, 1966

File N.I.H. Policy

February 16, 1966

INDIRECT COSTS, COST SHARING, AND EFFORT REPORTING: POLICIES AND PROCEDURES FORCED UPON THE UNIVERSITY AND THE FACULTY BY RECENT FEDERAL REGULATIONS WITH RESPECT TO RESEARCH GRANTS.

Federal government policies with respect to research grants (not contracts[1]) underwent significant revisions during 1965. Considerable confusion has surrounded some of these revisions, as unspecific Congressional actions and Congressional opinions were left to the Bureau of the Budget (BoB) to formulate as policy statements. These statements are in turn subject to interpretation by the agencies supporting research, and a further element of uncertainty is the unpredictable interpretation of the independent General Accounting Office auditors in allowing or disallowing charges under grants.

The significant areas of policy revision are the following:

1) Removal of statutory limits on payment to universities of full indirect costs.
2) Requirement of cost-sharing by universities.
3) Requirement of increased record-keeping, including after-the-fact review of percentage effort reports for faculty members and auditable records of the university's contribution to the research.

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1 Research contracts remain on a full cost-reimbursable basis, with full indirect costs as determined by the audited and approved rate.

The relevant government policy statements specifying these revisions are BoB Circular No. A-21 (Revised) dated March 3, 1965, and BoB Circular No. A-74 dated December 13, 1965.

There has been extensive study and discussion within the administration and staff, including discussion with faculty members, as to how Washington University can conform to these new requirements with a minimum of interference with primary faculty duties and with a minimum of added administrative cost to the university.

This memorandum sets forth the resulting policies and procedures. We may be able to improve upon them with experience, and we will welcome suggestions for any modifications which can reduce demands on faculty time or reduce the cost of administering the procedures.

1. Removal of statutory limits on payment of indirect costs

Congress did not include in the appropriation bills for fiscal year 1966 the limitations on indirect cost payments which had been incorporated in earlier years. These limitations typically allowed no more than a sum equal to 20% of direct costs to be paid toward indirect costs. Circular A-74 states that agencies "may" pay full indirect costs associated with research performed under grants. These costs are determined by using the auditing guidelines provided by Circular A-21 (Revised). Note that agencies are not required to pay full indirect costs, although the Congressional action puts considerable moral pressure on the agencies to do so.

Under the procedures of Circular A-21 (Revised), the latest Washington University approved indirect cost rate is 55 per cent of salaries. All indications are that most agencies will require use of salaries, rather than total

direct costs, as the base for computing indirect costs. This is also the Washington University preference.

As explained in the following section, Washington University will meet cost-sharing requirements by supplying a portion of the indirect costs in support of the research. These costs are quite as real as the direct costs, a fact which is clearly recognized by Circulars A-21 and A-74.

II. Cost Sharing by the University

Circular A-74 states that Federal agencies shall not pay any research grant recipient "an amount equal to as much as the entire cost of such a project," and that "the applicant institution must share in such research costs on more than a token basis." Congressional discussions indicated that 5%, or perhaps even as little as 1%, represents more than a token, but no specific percentage appears in A-74. (NSF required at least 5% in a provisional policy statement of September 22, 1965, but that statement has now been superseded by one using the phrase "more than a token".)

Washington University recognizes that research is one of its primary functions, and it therefore approves the principle of sharing in the cost of research projects undertaken with grant support. Program officers of the agencies have in the past urged substantial cost participation by the university. In spite of guidelines offered by the university administration since 1956 and earlier, the facts have been that Washington University has participated in a substantially greater percentage of the cost of government-supported research than many comparable institutions - far more than "token" participation. This fact and the large operating deficit require the university to adopt and adhere to a policy consistent with both Federal regulations and the university's financial means.

Bureau of the Budget Circular A-74 states that Federal agencies shall require that each research grant proposal include the following items:

"(1) The amount requested for direct expenses, by category of direct expenses.

(2) The amount requested for indirect expenses related to the requested direct expenses.

(3) The total grant request.

(4) The additional amount which the grantee institution proposes as its contribution from non-Federal sources to the planned research."

After carefully considering the advantages and disadvantages of various cost-sharing procedures, the university administration has adopted the following cost sharing principle for Washington University: TO ASSURE ITS PARTICIPATION TO THE EXTENT OF MORE THAN A TOKEN AMOUNT, WASHINGTON UNIVERSITY WILL PARTICIPATE IN RESEARCH SUPPORTED BY FEDERAL GRANTS THROUGH PROVIDING ONE-FIFTH (20%) OF THE INDIRECT COSTS ASSOCIATED WITH THE DIRECT COSTS OF THE RESEARCH. This policy has also been approved by the Dean of the School of Medicine and the Vice Chancellor for Medical Affairs.

A sample budget will illustrate how the cost sharing is to be presented in a research proposal:

I. Direct Costs		
A. Salaries and wages (Show name, position, per cent of salary - Academic year or Summer)	20,000	
B. Consumable supplies (Detail)	1,500	
C. Other Expense (Detail)	2,500	
D. Equipment (Itemize)	3,000	
E. Travel (Detail)	700	
F. Fringe Benefits (Annuity and Social Security)	1,500	
Total Direct Costs		29,200
II. Indirect Costs		
DoD Audited Rate 55% of Salaries and Wages		11,000
III. Total Cost of the Research		40,200
IV. Cost Shared by Washington University 20% of Indirect Costs		2,200
V. Requested (Agency) Support		38,000

The salaries listed under direct costs include the entire portion of faculty effort devoted to the research during the academic year, as well as summer salary for faculty research. In a typical department participating in sponsored research on the Lindell-Skinker campus, normal university expectation would be that a faculty member would divide his effort about equally between teaching and research. He would on that basis apportion about half of his academic year salary to research grants. There will be exceptions to this general expectation if he has substantial departmental administrative or teaching responsibilities (less effort to be charged to research grants)

or in a few special instances where he is primarily engaged in research (more than half of his effort to be charged to research grants). Training grants, not discussed in this memo, pay for portions of time devoted to teaching or training.

When agency program officers wish to support a project but state that they do not have funds for the full amount requested, university policy is that the 20% portion of indirect costs as the university's cost-sharing contribution is not negotiable. Any reduction in the total grant amount will therefore have to occur in direct cost categories. (To the extent that salary items may be eliminated, the agency payment of indirect costs will of course be correspondingly reduced.)

In the sample budget presented above, the university shares 5.5 per cent of the $40,200 total cost of the research. In our past experience, about 60 per cent of our research grant funds have been expended for salaries. On that basis, the contribution of 20% of the related indirect costs by Washington University would lead, with the present 55% indirect cost rate on salaries, to an overall cost sharing by Washington University of 6.2%.

We believe that this policy has several advantages over alternative cost sharing procedures. It does not require establishment in advance of a special cost-sharing pool of university dollars, because cost-sharing occurs automatically as each salary dollar of the grant is spent. It minimizes the budget transfers and fringe benefit computations which are necessary when a new grant is established. It permits a faculty investigator to add a new grant in support of his research without significantly jeopardizing previously existing cost-sharing commitments on grants already held.

III. Effort Reporting

Circular A-21 (Revised) requires after-the-fact review of effort of faculty members in research receiving grant support. Circular A-74 requires that the full cost, including academic year effort, be specified and auditable. Whereas the U.S. Public Health Service has required effort reports for some time, the new BoB regulations apply to all agencies.

In order to determine the indirect cost rate under Circular A-21 (Revised), the university continues to need estimates of the percentage of faculty effort devoted to departmental administration.

To meet these new effort-reporting requirements, the Budget Office will submit a list of his faculty members to each Department Chairman (or Dean for non-departmentalized schools) who will ascertain whether or not the previously determined distribution of effort by his faculty (among teaching, departmental administration, and various research projects) was in fact valid for the preceding report period. If so, he will sign the list and return it. If not, he will indicate corrections, and salary-charge adjustments for the research grants will be made so that no grant is charged for more effort than was actually expended.

This reporting, according to Circular A-21, should be done at least quarterly. Discussions with several deans and department chairmen indicate that the frequent changes of faculty effort assignment, as new grants are awarded and previous grants terminate, will probably cause monthly reporting to be simpler for the department chairmen and deans. Any changes to be introduced after-the-fact on a quarterly basis would affect several monthly

salary charges to grants; and the Federal fiscal quarters do not coincide with any normal division of the academic year or with pay periods.

Similar effort reporting is also required for non-professional staff.

Further information on the forms and procedures for use in effort reporting will be forthcoming from the Budget Office, which will work with the department chairmen in meeting these onerous new Federal requirements.

IV. Summer Research Pay for Faculty Members

The new effort reporting requirements apply to summer research activity as well as to the academic year. It remains university policy to allow, for faculty members on nine-month appointments, up to three months of summer pay on grants or contracts, provided of course that the three months of research effort is put forth. At least one agency, NSF, will pay for only two months of summer salary. Each month, or fraction thereof, of summer research activity is compensated at the monthly rate corresponding to the academic year (nine-month) salary.

V. Research Contracts

Federal policy has always permitted full cost reimbursement of the university by the contracting agency. It remains university policy to request full costs, direct and indirect, under research contracts. Restrictions on grants may quite possibly exceed those on contracts. The faculty should consider the desirability of requesting contracts from agencies, such as the Army Research Office or the Air Force Office of Scientific Research, that will write either a grant or a contract for a given project.

G. E. Pake
Provost

WASHINGTON UNIVERSITY

ST. LOUIS, MISSOURI 63130

OFFICE OF THE PROVOST

February 16, 1966

To: Faculty members participating in sponsored research

From: G. E. Pake

Subject: Washington University's Contribution to Grant-supported Research (Cost Sharing).

Introduction

During the academic year 1965-66, I estimate that Washington University contributed at least $4 million to research projects receiving grant support. The newly stated Federal requirements of cost sharing "on more than a token basis" would easily have been met by a Washington University contribution of only $1 million to these projects.

Several outstanding private universities with which Washington University competes for faculty and students have long been sharing fewer research costs, to an extent comparable to a $1 million contribution by Washington University. The institutions I have in mind have salary scales rated A in the AAUP salary survey. Washington University's average salary is rated at about B+, and Washington University had an operating deficit exceeding $2 million during 1965-66. There is reason to believe that, if Washington University had not made such large contributions to grant-supported research projects over the past several years, its salary rating might also be A.

It is with the foregoing thoughts in mind that the administration has adopted the accompanying policy statement on cost sharing in response to the new

regulations set forth by the Bureau of the Budget. During the first semester of 1965-66 the members of the administrative staff have expended a great deal of effort trying to understand a rapidly changing state of affairs and trying to determine the optimum response of Washington University to it. The staff from the Comptroller's Office, Funds Accounting Office, and the Budget Office have put in many hours helping the administrative offices of the university to understand intricate Federal policies and practice, and to understand the probable implications of various possible university policies.

I have personally discussed "cost sharing" questions with staff members of the Bureau of the Budget, with the President's Science Adviser, with the Director of the NSF, with the Chairman of the AEC, and with many other government officials. Dr. Hazzard and I, with co-sponsorship of the Stanford administration, called a special meeting of provosts, academic vice presidents (and similar types) from about 30 universities last October to discuss the problems and the implications of possible courses of action. It is clear that no single policy would serve all universities optimally.

Background

After years of pressure from universities through such associations as the American Council on Education (ACE) and the National Association of College and University Business Officers (NACUBO), Congress removed the limitations on indirect costs which even the government's formulae and auditing procedures had clearly established as real costs. But a kind of Pandora's box was inadvertently opened when Congress stated that, while Federal agencies can pay full indirect costs, they should not pay all of the costs of research done under grant support, and that the universities should share costs "on more than a

token basis." When it further emerged that 5% or perhaps even as little as 1%, would satisfy the cost-sharing requirement, the stage was set for complete confusion.

The confusion arose in part because Congress did not appropriate additional money to pay the full indirect costs it said agencies could now pay. Furthermore, some of the universities that had been sharing direct costs far in excess of the guidelines offered by Congress wondered why they should contribute more than other comparable (or shall I say competing?) universities. It was natural for them to contemplate recovering a larger portion of the costs. But again Congress had not appropriated funds for this, which it did not anticipate because it probably did not know the large extent to which some universities were already bearing costs for grant-supported research.

Although one might think that universities should long ago have had a clear policy on cost-sharing, there are many reasons why a written statement has not existed. When sponsored research entered the universities after World War II the small extent of involvement did not merit a policy statement: a good university, in the interest of maximum flexibility, is not quick to rigidify itself with policies, regulations, and restrictions. When involvement became great, and a carefully formulated policy might have provided clarification, the variety of restrictions and procedures used by the various Federal agencies made it practically impossible for a university to have a single policy.

One cannot in fairness blame the Federal agencies for all of the confusion. Typically, all over the nation, faculty members have wanted to have a maximum fraction of the grant funds at their own disposal for the research; they have

therefore sought to minimize use of grant funds for full indirect costs or for payment of a portion of relevant faculty salaries during the academic year, even though these costs are legitimate charges to the research project.

Many university administrations in the U.S. have tried to persuade professors on these matters, usually short of stating a policy that would become a cause celebre with those faculty members who did not want to be persuaded. Such administrative restraint (timidity?) notwithstanding, there are several top ranking private universities such as Chicago and Stanford, as well as the prestige institutes of technology in Pasadena and Cambridge, which have had reasonably clearcut practices of charging a substantial portion of the academic year salary to research grants, provided of course that the charge does not exceed the effort expended on the research. A new and high prestige campus of the University of California has such a policy even with its access to lavish state funds.

The extent of past cost sharing by Washington University

Official urging at Washington University that the relevant portions of faculty salaries ought to be charged to research grants and contracts dates back to 1956 and earlier. But the absence of any Federal guidelines (even such as participation shall be "more than a token") has permitted Federal agency program officers and some faculty members to insist that the university should extensively share in research costs for projects receiving grant support. As a consequence, I estimate that, in 1964-65, about $2 million (and perhaps as much as $3 million) in faculty effort was contributed by Washington University to research projects receiving grant support.

We know from the audited and approved overhead rate that Washington University contributed another $2 million through unreimbursed indirect costs. (Bear in mind, too, that the final indirect cost rate approved after our audit under Circular A-21 is one negotiated downward by Federal auditors, who disallow some items the university feels are legitimate charges under A-21.)

I conclude from the figures in the foregoing paragraphs that Washington University participated in sponsored research during 1964-65 to an extent of perhaps 25% or 30% of the total cost of the research. This far exceeds a "token". Moreover, we know that wealthier institutions such as Stanford and Chicago did much less sharing. (I have reliable information that one of these institutions did not share as much as 5%.)

There are other universities which do contribute as large a percentage in addition to research grant funds as Washington University, for example, Harvard University (with well over $1 billion in endowment).

Should Caltech, Chicago, MIT and Stanford be criticized for sharing a smaller fraction of research costs than does Harvard or Washington University? Such criticism, it seems to me, would in effect argue that those four institutions have not benefitted the nation by carrying on the more extensive and higher quality programs afforded by fuller use of the sponsoring-agency dollar. Harvard enjoys the freedom conferred by extreme wealth, and it can thus afford to choose another course of action.

The accompanying statement of Washington University policy with respect to cost sharing is necessitated by the new developments with respect to Federal policy on indirect costs and cost sharing. The policy reflects conclusions drawn

from comparisons with other private universities of approximately comparable aims and quality standards (if greater wealth) and from the large size of the current Washington University operating deficit.

The accompanying policy statement will not be easy to implement. It is clear that BoB Circular A-74 tries to freeze the status quo insofar as Congressional intent will allow, simply because Congress did not appropriate the additional funds with which to pay full indirect costs, let alone to permit universities which had previously done excessive cost sharing to adjust to a norm commensurate with their means. As a consequence, the next year or two will be a period of extensive negotiation with agencies and their program officers. It is part of the price we pay for not having adhered in practice to the policy urged from time to time since the early 1950's.

GRANT A

Column 1 - Grant as awarded

Column 2 - Grant under new cost-sharing plan without principal investigator's salary

Column 3 - Grant under new cost-sharing plan with principal investigator's salary

	1	2	3
Principal Investigator (30%)	$ 0	$ 0	$ 5,400
Other Salaries	22,350	22,350	22,350
Other Direct Costs	29,909	29,909	29,909
Total Direct Costs	52,259	52,259	57,659
Indirect Costs			
20% of TDC excl.renovations	8,309		
55% of Salaries		12,292	15,262
Total Cost of Project	60,568	64,551	72,921
Cost-Sharing			
20% of Indirect Costs		2,458-	3,052-
Amount Realized by University	60,568	62,093	69,869
Per Cent of Cost-sharing by University		3.81	4.18

Column 3 versus Column 2

Net Gain in Overhead	$2,376
Savings in Principal Investigator's Salary	5,400
	$7,776

GRANT B

Column 1 - Grant as awarded

Column 2 - Grant under new cost-sharing plan without principal investigator's salary

Column 3 - Grant under new cost-sharing plan with principal investigator's salary

	1*	2	3
Principal Investigator (80%)	$ 0	$ 0	$ 8,000
Other Salaries	6,500	6,500	6,500
Other Direct Costs (including $31604 equipment)	38,386	38,386	38,386
Total Direct Costs	44,886	44,886	52,886
Indirect Costs			
20% of TDC	8,977		
55% of Salaries		3,575	7,975
Total Cost of Project	53,863	48,461	60,861
Cost-sharing			
20% of Indirect Costs		715-	1,595-
Amount Realized by University	53,863	47,746	59,266
Per Cent of Cost-sharing by University **		1.47	2.6

Column 3 versus Column 2

Net Gain in Overhead	$3,520
Savings in Principal Investigator's Salary	8,000
	$11,520

*This grant has been applied for - it has not been awarded to date

**Cost-sharing on this grant would be expected to be low because of large amount of equipment requested in first year of grant

GRANT C

Column 1 - Grant as awarded

Column 2 - Grant under new cost-sharing plan without principal investigator's salary

Column 3 - Grant under new cost-sharing plan with principal investigator's salary

	1	2	3
Principal Investigator (25%)	$ 0	$ 0	$ 7,000
Other Salaries	22,400	22,400	22,400
Other Direct Costs	7,112	7,112	7,112
Total Direct Costs	29,512	29,512	36,512
Indirect Costs			
20% of TDC	5,902		
55% of Salaries		16,231	20,081
Total Cost of Project	35,414	45,743	56,593
Cost-sharing			
20% of Indirect Costs		3,246-	4,016-
Amount Realized by University	35,414	42,497	52,577
Per Cent of Cost-sharing by University		7,09	7.09

Column 3 versus Column 2

Net Gain in Overhead	$ 3,080
Savings in Principal Investigator's Salary	7,000
	10,080

Grant D

Column 1 - Grant as awarded

Column 2 - Grant under new cost-sharing plan without principal investigator's salary

Column 3 - Grant under new cost-sharing plan with principal investigator's salary

	1	2	3
Principal Investigator (15%)	$ 0	$ 0	$ 2,850
Co-Investigator (5%)	0	0	1,150
Other Salaries	21,280	21,280	21,280
Other Direct Costs	11,547	11,547	11,547
Total Direct Costs	32,827	32,827	36,827
Indirect Costs			
20% of TDC less Hospitalization	5,525		
55% of Salaries		11,704	13,904
Total Cost of Project	38,352	44,531	50,731
Cost-sharing			
20% of Indirect Costs		2,341-	2,781-
Amount Realized by University	38,352	42,190	47,950
Per Cent of Cost-sharing by University		5.26	5.48

Column 3 versus Column 2

Net Gain in Overhead	$1,760
Savings in Investigators' Salaries	4,000
	5,760

SUMMARY

Washington University Policies for Research Grants:

Indirect Costs, Cost Sharing, Effort Reporting, Summer Salaries.

(Based upon the Provost's memo of February 16, 1966)

1. Full indirect costs are allowable. Although agencies are not necessarily required to pay them, indications are that most agencies will do so. The current university rate is 55% of salaries and wages charged to the grant.
2. Each investigator should charge to the grant a proportion of his academic year salary corresponding to his effort on the program sponsored.
3. Washington University's cost-sharing on each grant-supported program will be 20% of the indirect cost as computed in 1.
4. An illustrative proposal budget might be as follows:

I. Direct Costs		
A. Salaries and wages (Show name, position, per cent of salary - Academic Year or Summer)	20,000	
B. Consumable supplies (Detail)	1,500	
C. Other Expense (Detail)	2,500	
D. Equipment (Itemize)	3,000	
E. Travel (Detail)	700	
F. Fringe Benefits (Annuity and Social Security)	1,500	
Total Direct Costs		29,200
II. Indirect Costs		
DoD Audited Rate 55% of Salaries & Wages		11,000
III. Total Cost of the Research		40,200
IV. Cost Shared by Washington University 20% of Indirect Costs		2,200
V. Requested (Agency) Support		38,000

5. Monthly effort reporting, in order to comply with Bureau of the Budget Circular A-21 (Revised) and for developing data needed in computation of the indirect cost rate, will be required for faculty members and for non-professional staff. The department chairman need only indicate approval or changes in reports prepared by the Budget office.

6. University policy for faculty members on nine-month appointments permits up to three months of summer pay if three months of effort are put forth. The monthly rate is one-ninth of the academic year salary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
WASHINGTON, D.C. 20201

REFER TO:

February 8, 1966

TO : The Heads of Institutions Conducting Research with Public Health Service Grants

FROM : Surgeon General, Public Health Service

SUBJECT: Clinical research and investigation involving human beings

Expanding Public Health Service support of clinical research and investigation involving human beings emphasizes the need for more formal attention to the critical issues raised by such research.

In December 1965 the National Advisory Health Council, after study of these critical issues, made certain recommendations to me which I have now formulated as the following Public Health Service grant policy:

> No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination: (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of the associates who will provide the review shall be included in the application.

Effective immediately, this policy will be included in all future statements of Public Health Service research and research training grant policy. The wisdom and sound professional judgment of you and your staff will determine what constitutes the rights and welfare of human subjects in research, what constitutes informed consent, and what constitutes the risks and potential medical benefits of a particular investigation.

I wish to define more explicitly, however, what is meant by a committee of his institutional associates to assure an independent determination because the policy requires that the application include a description of the individuals who will provide the review. The committee would need to be made up of staff of, or consultants to, your institution who are at the same time acquainted with the investigator under review, free to assess his judgment without placing in jeopardy their own goals, and sufficiently mature and competent to make the necessary assessment. It is important that some of the members be drawn from different disciplines or interests that do not overlap those of the investigator under review.

The policy does not ask for the names of the members of the committee. It does ask for a description of its composition; e.g., the number of members and the professional or public interests they reflect.

I have directed all my staff who administer the initial review of applications for grants for clinical research and investigations involving human beings -- regardless of whether these applications are for new, supplemental, renewal, or continuation support -- to ascertain that each application includes the information required by this policy and to obtain this information, whenever necessary, in a document signed by both the principal investigator or program director and the official for the institution.

I know that you are as deeply concerned with this issue as are any of us in the Public Health Service. I urgently request that you give my staff your cooperation in making this policy an effective instrument for the good of the public and science.

William H. Stewart

William H. Stewart, M.D.

AM-06309-04

(Leave Blank)
R'cd date 11/2/61
Council Mar. 62
Action

U. S. Department of
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

APPLICATION FOR RESEARCH GRANT
(A PRIVILEGED COMMUNICATION)

No. A-6309
SS Nutr. (1)
Formerly

NRP-Yes

Application is hereby made for a grant in the amount and for the period stated, for the purpose of conducting research as described herein, in accord with the Agreement signed below.

A. AMOUNT REQUESTED: $ 45,444.00 (Same as total of itemized budget, page 2, item A8.)

B. PERIOD DATES: May (Mo.) 1 (Day) 1962 (Year) thru April (Mo.) 30 (Day) 1963 (Year) (Normally 12 months. See instructions.)

C. TITLE OF RESEARCH PROPOSAL (Do not exceed 53 typewriter spaces)
Diet and Enzyme Activity Within the Hepatic Lobule

D. TYPE OF APPLICATION (please check one only, and add No. if applicable): ☒ New Project Proposal; or ☐ Revision of, ☐ Supplement to, or ☐ Renewal of PHS application or grant No.

E. PRINCIPAL INVESTIGATOR:
Name Robert E. Shank, M.D. Telephone No. FOrest 7-6400 Extension 467
Title Danforth Professor of Preventive Med. Department or Service Preventive Medicine
Mailing address of Research office Euclid Ave. and Kingshighway
St. Louis 10, Missouri
Institution Washington University Major Sub Division School of Medicine

F. CO-PRINCIPAL INVESTIGATOR, if any. (Name and title only)
George R. Morrison, M. D.

G. INSTITUTION SPONSORING REQUEST
Name Washington University
Mail address Lindell & Skinker Blvd.
St. Louis 30, Missouri
Name & title of official authorized to sign application on behalf of institution Thomas H. Eliot
Vice-Chancellor, Dean of Faculties

H. NAME, TITLE, AND ADDRESS OF FINANCIAL OFFICER:
Merle M. Huntsinger, Comptroller
Washington University
St. Louis 30, Missouri
Manner in which check(s) should be drawn: (669312)
Washington University

I. AGREEMENT: It is understood and agreed by the undersigned that any grant received as a result of this application is subject to the following terms. (1) Funds granted as a result of this request are to be expended for research or related purposes as governed by Public Health Service and grantee institution policies; (2) the grant may be revoked in whole or in part at any time by the Surgeon General of the Public Health Service, provided that a revocation shall not include any amount obligated previous to the effective date of the revocation if such obligations were made solely for the purposes of research; (3) all reports of original investigations supported by the grant shall acknowledge such support; (4) if any invention arises or is developed in the course of the work aided by the grant, the undersigned will either (a) refer to the Surgeon General for determination, or (b) determine in accordance with grantee institution's own policies as formally stipulated in a separate supplementary agreement entered into between the Surgeon General and the grantee institution, whether patent protection on such invention shall be sought and how the rights in the invention, including rights under any patent issued thereon, shall be disposed of and administered, in order to protect the public interest.

J. PERSONAL SIGNATURES (in ink)
(1) Principal Investigator Robert E. Shank, M.D (Same as shown in "E" above) Oct. 27, 1961 (date)
(2) Authorized official of applicant institution Thomas H. Eliot (Same as shown in "G" above) Oct. 31, 1961 (date)

Mail completed application to:
Division of Research Grants
National Institutes of Health
Bethesda 14, Md.

NKB

A 6309

A. BUDGET REQUEST (for the period shown on page 1)

(1) 1. PERSONNEL List all positions, including Principal and Co-investigator. Amounts requested must not exceed proportion of total salary computed from % of time spent.	(2) % time on this project	(3) Requested from PHS (omit cents)
Robert E. Shank, M.D., Danforth Prof. of Preventive Medicine	20 %	$
George R. Morrison, M.D., Instructor of Med. & Prev. Med.	50 %	-----
Chuan Huan Cheng, Ph.D., Research Assistant	100 %	7500.00
Laboratory Technician	100 %	4500.00
Glassware Washer	25 %	800.00
Animal Caretaker	25 %	800.00
Social Security (3½%)	%	476.00
2. PERMANENT EQUIPMENT, itemize (see instructions)		
Microscope, Dissecting		$ 700.00
Cryostat and Microtome with annual repair		2500.00
Deep Freeze		250.00
Vacuum Pump		300.00
Built-in Laboratory Furnishings & Equipment		5000.00
3. CONSUMABLE SUPPLIES, itemize (see instructions)		
Animals		$ 1500.00
Animal Feed		300.00
Reagents, Supplies and Glassware		2000.00
4. TRAVEL, itemize (see instructions)		
For attendance at Scientific Meetings		$ 500.00
5. OTHER EXPENSE, itemize (see instructions)		
Renovation and building of Cold Dissection Room		$ 15,000.00
6. TOTAL DIRECT COST REQUIREMENTS		$ 42,126.00
7. INDIRECT COST ALLOWANCE (The administrative official signing this application may request an amount for indirect costs. Review detailed instructions) (Round to low dollar) 15% of $22,126		$ 3,318.00
8. TOTAL BUDGET (Same as amount shown in item A, page 1)		$ 45,444.00

B. ESTIMATE OF SUPPORT REQUESTED FOR THE YEAR FOLLOWING THE BUDGET PERIOD ITEMIZED ABOVE. Applicants for 1-year grants should type the word "None" in space for TOTAL BUDGET shown below.

Personnel	Equipment	Supplies	Travel	Other	Total Direct Cost	Indirect Cost	TOTAL BUDGET
$15,000	$ 1,000	$3,800	$ 500.	$ ---	$20,300	$3,045	$23,345

C. ADDITIONAL YEARS OF SUPPORT, beyond the 2 years covered above, if requested. Please show the TOTAL AMOUNTS required for each such additional year, including indirect cost allowance.

3. $ 24,500 4. $25,000 5. $ --- 6. $ --- 7. $ ---

RESEARCH SUPPORT

List all other research support of the Principal Investigator, including that from own institution, and applications that are pending. Use continuation page if necessary. See instructions.

A. PUBLIC HEALTH SERVICE SUPPORT:

GRANT NUMBER	TITLE OF PROJECT	AMOUNT	PERIOD OF SUPPORT
(1) Active or approved:			
2G-807	Epidemiology Training Grant	$49,000	7/1/61-6/30/62
(2) Applications submitted, awaiting decision:			
2A-5431(n)	Nutrition Training Grant	$45,208	7/1/62-6/30/63

B. ALL OTHER RESEARCH SUPPORT:

SOURCE	TITLE OF PROJECT	AMOUNT	PERIOD OF SUPPORT
(1) Active or approved:			
U.S.Army T117 PB	Quantitative Cytochemical Investigation of Activities of Certain Enzymes in Liver	$23,000	1/1/61-12/31/61
(2) Applications submitted, awaiting decision:			
U.S.Army T117 PB	Quantitative Cytochemical Investigation of Activities of Certain Enzymes in Liver	$38,720	1/1/62-12/31/62

45,044
23,345
24,500
25,000
118,289

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BIOGRAPHICAL SKETCHES

Provide brief sketches for professional personnel directly related who are to be actively engaged in this project. The following format should be used for each person, with Co-Investigator if any immediately following Principal Investigator, then other professional personnel, lettered consecutively.

A. Principal Investigator: Robert E. Shank, M.D.
(Name and title)

1. Date of birth: 9-2-14 Place of birth: Louisville, Kentucky
Present nationality: United States Male Female

2. Educational experience:

a. Degrees obtained (Begin with baccalaureate degree. Identify honorary degrees under field.)

DEGREE	INSTITUTION (AND LOCATION)	FIELD	YEAR
B.A.	Westminster College	Pre-Medical	1935
M.D.	Washington University	Medicine	1939

b. Other research training and experience especially that establishing research qualifications in area covered by this application

WHERE	NATURE	YEAR
Rockefeller Institute	Studies of Diseases of Liver and Muscle	1941-1946
Public Health Research		
Institute of City of N.Y.	Nutritional Disorders	1946-1948

3. Fields of present major scientific interest, in order of choice:
Nutrition and Hepatic Disease

4. Supplemental information:

B. George Robert Morrison, M.D.
(Name and title)

1. Date of birth: 12-2-25 Place of birth: Camden, New Jersey
Present nationality: United States Male Female

2. Educational experience:

a. Degrees obtained (Begin with baccalaureate degree. Identify honorary degrees under field.)

DEGREE	INSTITUTION (AND LOCATION)	FIELD	YEAR
B.A.	University of Rochester	Pre-Medical	1948
M.D.	University of Rochester	Medical	1954

b. Other research training and experience especially that establishing research qualifications in area covered by this application

WHERE	NATURE	YEAR
Washington University	Research Fellow	1957-1959
University of Rochester	AEC Research Assistant	1949-1950

3. Fields of present major scientific interest, in order of choice:
Hepatic Diseases

4. Supplemental information:

RESEARCH PLAN AND SUPPORTING DATA

Inside of the proposed plan and other necessary data should be typed single spaced in accord with the outline below, which is suggestive only. Use numerals. Please continue numbering pages in sequence for entire application. Additional continuation sheets, if needed, may be requested from the Division of Research Grants.

I. RESEARCH PLAN

A. **Specific Aims** - Provide a concise statement of the aims of the work immediately proposed and relate these to your long-term goal.

B. **Method of Procedure** - Give details of your research plan, including how results will be analyzed. For work specific aim mentioned in "A" show how your plan is expected to fulfill the aim.

C. **Significance of the Research** - Explain why the results of the proposed work may be important.

D. **Facilities Available** - Describe the general facilities of your research. List the major items of equipment appropriate

II. SUPPORTING DATA

A. **Previous Work Done on this Project** - Describe briefly any work you have done to date that is particularly pertinent.

B. **Results Obtained by Others** - Summarize important results to date obtained by others on this problem, citing publications. Select no more than five.

C. **Personal Publications** - List your most important publications on this or closely related work. List no more than five.

D. **Justification of Budget** - Indicate requested budget for the initial period (A, page 2) whose you feel it necessary, and delineate necessary items to budget estimates for continuation years.

I. RESEARCH PLAN

A. **Specific Aims** - The aims of this investigation are:

1. To determine the effects of various dietary contaminants upon the activities of enzymes within groups of hepatic cells in central, midzonal and portal areas of the normal hepatic lobule.

2. To determine the effects of various diets and nutrients in establishing susceptibility of various portions of the normal liver lobule to injury.

3. To characterize the changes in enzyme activity within the hepatic lobule which precede and accompany nutritional liver injury.

4. To determine the enzyme activities of groups of liver cells in active phases of regeneration.

5. To assess the effects of various diets and nutrients on the process of regeneration following liver injury.

B. Method of Procedure

Microchemical methods have been adapted in the Nutrition Research laboratories of the Department of Preventive Medicine for the determination of the activities of a number of enzymes and the concentrations of various constituents of hepatic cells dissected out from central, midzonal and portal areas of the liver lobule. The methods utilized are adaptations of the procedures originally described by Hilmoe H. Lowry and his associates. The specimen of liver taken for analysis is dropped immediately into liquid nitrogen. Microsections are cut in a cryostat at a temperature of -25°C. The tissue sections are dehydrated in vacuo at -40°C. After dehydration sections are brought to room temperature in vacuo and representative areas of the lobule are dissected out at a magnification of 72X under a dissecting microscope. The lobular segments are then weighed on a quartz beam balance. The dry weight of individual sections varies from 0.25 to 2.1 micrograms. One or more sections are utilized in the microchemical analyses. All analyses are done in triplicate.

The microchemical procedures previously adapted in this laboratory permit determination of the following enzyme activities: alkaline phosphatase, glucose-6-

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phosphate dehydrogenase, phosphoglucoisomerase, lactic dehydrogenase, malic dehydrogenase, isocitric dehydrogenase, glutamic dehydrogenase, glutamic-pyruvic transaminase, glutamic-oxalacetic transaminase and beta-hydroxybutyryl-Co-A-dehydrogenase. In addition concentrations of protein, cholesterol and DNA are determined. Activities of enzymes may be expressed in terms of dry weight of the tissue, protein, or DNA. Methods are also available for determination of coenzymes, such as DPN, TPN and FAD, in liver tissue as well as the total hemoglobin, lipid and cholesterol content. It would be proposed during the course of this investigation to develop methods for determination of additional enzymes and cell constituents. Concurrent with the microchemical determinations, adjacent microsections of liver are stained with histologic stains for evaluation of cellular morphology, as well as content and distribution of lipid.

In these experiments liver tissue will be obtained from young Sprague-Dawley rats. The influence of various carbohydrates and fats and of varying quantities and quality of protein in isocaloric diets upon activity of each of the enzymes in different areas of the liver lobule will be determined. A single modification of diet will be made in an experiment. All of the diets provided will afford adequate daily intake of calories, minerals and vitamins. All modifications of diet will utilize as control a standard semi-synthetic laboratory diet which has in the experience of this laboratory been proven adequate to sustain normal growth and development without histologic abnormality in liver. Control animals will be pair fed with experimental animals. Groups of control animals will be made up of the same number of animals as experimental groups. All diets will be fed for a minimum period of one month before the animals are sacrificed and determinations made. Differences will be assessed utilizing standard statistical procedures. It is hoped that by these approaches the degree of dependence of activities of enzymes in liver upon energy sources in the diet may be ascertained and conversely the adaptability of these enzymes to changes in diet composition will be determined.

If it is ascertained that diets of known compositionreproducibly account for variations in activity of certain of the enzymes within specific portions of the liver lobule, the relative susceptibility to liver injury will be investigated. If the change produced is most notable in central areas, carbon tetrachloride, a centrolobular toxin, will be utilized and administered to experimental and control animals. The extent of histologic damage, as well as the changes produced in enzyme activities, will be compared. Similarly, liver necrosis induced by phosphorus in periportal areas and by ethionine in central areas may be investigated.

Other experiments will deal with characterization of the changes in enzyme activity which are produced in various portions of the liver lobule by the device of nutritional liver damage. These lesions will be induced through use of a high fat - low protein diet, a choline deficient diet, alcohol ingestion, and/or a Factor 3-selenium deficient diet in different experimental groups. Animals will be sacrificed at intervals before and after evidence of histologic damage has occurred so that changes in activity of enzymes preceding cell necrosis may be determined.

Another phase of these investigations will be concerned with characterization of enzyme activities of groups of liver cells from various portions of the lobule during phases of regeneration following partial hepatectomy or sublethal necrosis produced by hepatotoxins or nutritional deficiency. In addition the effects of diets varied in quantity and quality of carbohydrates, protein and fat on the enzymatic changes found to characterize regeneration will be evaluated. In other experiments the possible effects on regeneration of supplements such as various B vitamins, vitamin E and Factor 3-selenium will be tested.

C. Significance of this Research-

Various types of liver injury are characterized by lesions beginning in or most pronounced in central, mid-zonal or periportal areas of the hepatic lobule.

The hypothesis to be tested in these experiments is that the metabolic activity of hepatic cells is determined by their position within the lobule and accounts for relative susceptibility or resistance to liver injury. As a means of comparing metabolic activities of liver cells from different lobular areas, we have chosen to determine activities of certain enzymes with key roles in metabolic systems. Moreover, it is likely that enzyme activities within the lobule reflect the nature or composition of the diet. Prior investigations in this and other laboratories approaching these problems utilizing homogenates of liver or histochemical staining procedures have provided certain kinds of information but do not permit as effective an approach to the problem of coexisting lesions of degeneration and regeneration within the lobule as do microchemical procedures which afford information at the cellular level.

Information of the kind sought in the investigations proposed should provide more complete understanding of the susceptibility of liver to various types of injury and might hopefully lead to new approaches to therapy of liver disease through elucidation of nutritional factors important to processes of regeneration.

D. Facilities Available

A laboratory is available which is equipped for microchemical procedures. Included are micropipettes, quartz beam balances, microfluorometer, Beckman spectrophotometer, refrigerated centrifuge, pH meter, etc. The facilities of Dr. O. H. Lowry in the Department of Pharmacology have been previously utilized for microsectioning, microdissection and dehydration of tissues. This has been done with some inconvenience since the two laboratories are in separate buildings one block apart. The facilities in the Department of Pharmacology are currently utilized to fullest extent and it is necessary for the Nutrition Research Laboratories to afford new facilities to meet its own needs. This can be done in space recently made available immediately adjoining the laboratory, through removal of the University Clinics to a new building. Accordingly, funds are requested for renovation and equipping of this space to afford a new laboratory with temperature and humidity control for microdissection and weighing and a cold room for microsectioning. A portion of the funds requested for renovation would be used to enlarge an existing but badly crowded animal room.

Advice and consultation in experimental design and statistical analysis is available through Mrs. Barbara Dixon, a statistician, who is a member of the staff of this department. Moreover, invaluable assistance and advice concerning technical procedures of microchemical analysis is readily available through Dr. O. H. Lowry and his associates.

II. SUPPORTING DATA

A. *Previous Work Done on this Project*

During the past four years this laboratory has been engaged in development and adaptation of microchemical methods for determining the activity of ten different enzymes and other cell constituents in groups of liver cells taken from various portions of the lobule in normal rats and in humans without liver disease. Variations in activity of certain of these enzymes between central and portal areas have been determined in both species. In general, enzymes which participate in aerobic systems such as isocitric dehydrogenase, malic dehydrogenase and glucose-6-phosphate dehydrogenase have relatively greater activities in centrolobular areas, while enzymes which are able to maintain function under more aerobic conditions, i.e., - phosphoglucoisomerase, lactic dehydrogenase, and glutamic pyruvic transaminase, have greater periportal activity. Differences between species have also been noted. For instance, alkaline phosphatase has greatest activity in portal areas in the rat but in central areas in man. Other observations utilizing homogenates of livers of rats fed various types of carbohydrates have demonstrated adaptability of enzyme activity to the food ingested. This was done as a trial

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observation before proceeding to microchemical studies of this phenomenon.

B. Results Obtained by Others

1. M. V. Buell, O. H. Lowry, N. R. Roberts, M-L. W. Chang and J. I. Kapphohn, The Quantitative Histochemistry of Brain. J. Biol. Chem. 232:979-993,1958.

New microchemical techniques for the estimation of seven enzymes important in the four main channels of glucose utilization are described. This paper includes important references to the general techniques for measuring enzymatic activities on the required microscale.

2. A. B. Novikoff and E. Essner, The Liver Cell. Am. J. Med. 29:1960.

Applying histochemical staining procedures to freshly fixed normal rat liver sections, localization of five enzymes was possible within the hepatic lobule. Activities of glucose-6-phosphate dehydrogenase and ATPase were greatest in areas of largest concentration of glycogen (periportal). Reduced pyridine nucleotides were noted to be in highest concentration in central areas.

3. J. C. Waterlow and S. J. Patrick, Enzyme Activity in Fatty Livers in Human Infants. Ann. N. Y. Acad. Sci. 57:750, 1954.

Activities of a number of enzymes in homogenates of liver biopsy specimens taken from patients with kwashiorkor were measured. Activities of Choline esterase and succinoxidase were reduced while those of malic dehydrogenase and transaminase were increased.

4. W. M. Fitch, R. Hill and I. L. Charkoff, Hepatic Glycolytic Enzyme Activities in the Alloxan-diabetic Rat: Response to Glucose and Fructose Feeding. J. C. I. 234:2811, 1959.

Responses of five hepatic glycolytic enzymes were determined to a hexose-free diet, 60% glucose diet and 60% fructose diet. Moderate elevations in phosphoglucoisomerase and marked elevations in glucose-6-phosphate dehydrogenase occurred with fructose in the diet. Effects were significantly diminished in the alloxan-diabetic rat liver.

5. E. Schmidt, F. W. Schmidt and E. Wildhirt, Aktivitats - Bestimmungen Von Enzymen Des Energieliefernden Stoffwechsels Bei Chronischen Leber-Entzundungen. Klin. Wschr. 36:611, 1958. Ryser 1958

The activities of ten enzymes in homogenates prepared from needle biopsies of human liver are compared not only in specimens from normal subjects but also in biopsies obtained from patients with a variety of chronic hepatic diseases.

C. Personal Publications

3) 1. R. E. Shank, George Morrison, Chuan Huan Cheng, Irene Karl and Ruth Schwartz, Cell Heterogenity within The Hepatic Lobule (Quantitative Histochemistry). J. Histochem. and Cytochem. 7:237, 1959.

4) 2. George Morrison, Irene Karl, Ruth Schwartz and R. E. Shank, Enzymatic Activity within The Human Hepatic Lobule. J. Lab. and Clin. Med. 54:928, 1959.

5) 3. I. E. Karl, R. Schwartz, S. M. McNicol, H. Zarkowsky and R. E. Shank, The Effect of Carbon Tetrachloride on Enzymes and Biochemical Constituents of Rat Liver. Fed. Proc. 20:287, 1961.

1) 4. R. E. Shank, Viral Hepatitis. Disease-A-Month Series, Sept. 1955.

2) 5. C. L. Hoagland and R. E. Shank, Infectious Hepatitis: A Review of 200 Cases. J.A.M.A. 130:615, 1946.

D. Justification of Budget-

No 6 - 15 hours

The budget as prepared provides for the employment of Dr. Cheng, a biochemist, as research assistant. She had earlier experience in this laboratory in the development of microchemical procedures. She left the laboratory four years ago to care for her family and now is able to return to employment. Her services would be invaluable to the investigation.

The continuation and extension of this research interest of this department is contingent upon its being able to provide its own facilities for preparation and

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microdissection of tissues. Previously this had been done in laboratories of Dr. Lowry in the Department of Pharmacology. Those laboratories are located at a distance of a city block from the Department of Preventive Medicine and are utilized intensively. Space immediately adjoining the Nutrition Research Laboratories has been made available for development of new research facility. Previously this space had been utilized by the Washington University Clinics and was vacated in May 1961 when a new clinic building was completed.

The appropriation requested includes in the first year's budget $15,000 for renovation and $5,000 for equipment of this space. To be built with these funds would be a small cold room maintained at -20°C (6 x 10 feet) which would be utilized for microsectioning and preparation of tissue. In addition a small air-conditioned laboratory (approximately 10 x 15 feet) would be built and equipped to serve purposes of microdissection and weighing. The most important new equipment to be placed in this laboratory are a cryostat and a microtome, neither of which is now available to these laboratories. Quartz beam microbalances for weighing small sections are currently in our laboratory and additional ones would be constructed as needed.

The budgets of future years contain no funds for renovation and allow only for replacement and maintenance of equipment. It is not proposed to add to the group of research personnel in future years but budgets allow for salary increments.

DO NOT TYPE IN THIS SPACE - BINDING MARGIN

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
WASHINGTON, D.C. 20201

BUREAU OF STATE SERVICES

REFER TO:

K L
11-22
→ Dr Shonk
We are not
involved in any such
project - are we?

Gentlemen:

We think you will be interested in the Health Economics Studies Information Exchange being established in the Division of Medical Care Administration.

The purpose of this Information Exchange is to collect and disseminate information concerning current studies on health economics and medical care, in order that the scope of communication between researchers in these fields may be broadened. Enclosed is a brief statement entitled "Purpose and Method of Operation."

We need your assistance in obtaining information about current studies. Please use the enclosed "Health Economics and Medical Care Study Notice" form for reporting projects with which you are concerned. With the form is a list of the major areas of interest of this Exchange. If you are not now involved in such projects but know of others in your organization who are, please pass the form on to them.

DO NOT
If neither you nor your associates engage in studies of health economics or medical care, please note this fact in the space provided on the form. Your name will be removed from the Information Exchange mailing list until you request its inclusion again.

An addressed envelope requiring no postage is enclosed for your use.

Sincerely yours,

Returned
12/15/65

Health Economics Studies
Information Exchange
Health Economics Branch
Division of Medical Care
Administration

Enclosures

Purpose and Method of Operation

of the

Health Economics Studies Information Exchange

This Exchange will be valuable to those interested in the supply, demand, utilization, administration, organization and financing of community health services and medical care. Its objectives are:

1. To provide a systematic method of informing workers in the public health and medical care field where specific data on health economics and medical care may be secured;

2. To afford a convenient means whereby those who are planning studies involving the financing, utilization and organization of community health services and medical care can get in touch with others who have undertaken similar investigations.

The Exchange will periodically survey universities and colleges with departments of economics, business administration, schools of public health, public administration, medicine, pharmacy, nursing, and optometry located in the U.S. and Canada; State and large-city health departments; selected governmental and nongovernmental research agencies; and the Public Health Service.

Abstracts of new projects will be released from time to time, describing current work in health economics and medical care. Such information will not be published without the permission of those responsible for the study, unless a description of the project has already been published. If the Exchange prepares an abstract from the published material for inclusion in the Information Exchange, the source of the report used will be cited.

One report form should be completed for each study to be submitted to the Exchange. Requests for blank forms or information may be directed to: Health Economics Studies Information Exchange, c/o Health Economics Branch, Division of Medical Care Administration, Public Health Service, U.S. Department of Health, Education, and Welfare, Washington, D.C. 20201.