DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

2/24

National Institutes of Health
Bethesda, Maryland 20892
Building ORS :
Room :
(301) 496-

FEB 25 1991

1991 FEB 26 P 2:45

TO: Donald A. B. Lindberg, M.D.
Director, National Library of Medicine

FROM: Acting Director, NIH

SUBJECT: Space Requirements for the National Library of Medicine

Thank you for your December 20 memorandum requesting that space on the B2 level of Building 38A be reassigned to the NLM when the NIH National Historical Office relocates to Building 31. The pressing need for additional space is an issue that is affecting all of NIH.

When the Fogarty International Center vacated Building 38A, their space on the sixth floor was backfilled by the National Center for Human Genome Research (NCHGR). Approximately 2,000 square feet on the B2 level was divided between the NLM and the Director's Reserve. This assignment was made in order to provide you with some relief while allowing us the opportunity to assess future space needs for NCHGR.

As a relatively new program, the Center has recently experienced tremendous growth in personnel, requiring additional space. Because it is a small program, it cannot effectively manage its resources if split into two remote locations. For this reason, I am reassigning the space on the B2 level to NCHGR.

My decision does not mean that we see the NLM shortage as less severe than NCHGR's; it is just that, at this time, we believe the size and stability of your organization will allow you to absorb the shortage better than can NCHGR. Should the Center outgrow the sixth floor and B2 level space and need to relocate, and all other factors remain about the same, I would support the reassignment of this space to you.

I have asked the Division of Engineering Services (DES) to explore options for resolving your computer room problems until space is available. Your staff could contact Mr. Tony Clifford in DES (496-6186) or Mr. Paul Horton in the Division of Space Management (496-3172).

I appreciate your understanding in this matter.

/s/ William F. Raub, Ph.D.

William F. Raub, Ph.D.

cc:
Dr. Elke Jordan, NCHGR
Mr. Norman Mansfield, ORS
Mr. Anthony Clifford, DES
Mr. Paul Horton, DSM

[redacted] scribed by NIH Manual 1121

NOTIFICATION OF ORGANIZATION CHANGE

1. To *(title, BID, and building/room)*

Director, National Center for Human Genome Research

2. Type of Change

- ☒ Abolish organizational component
- ☒ Establish organizational component (functional statements are attached)
- ☐ Transfer organizational component
- ☐ Title change
- ☐ Revision of functional statement (functional statements are attached)

3. Approving Authority

Secretary, DHHS

4. Effective Date

October 1, 1989

5. The Standard Administrative Codes:

- ☒ which were assigned to abolished organizational components have been deleted and are listed below.
- ☒ which were assigned to established organizational components are listed below.
- ☐ which were assigned to transferred organizational components are listed below.
- ☐ have not been changed; however, organization title changes have been made and are listed below.
- ☐ have not been changed since no organizational components have been established or abolished. The existing codes are noted on the attached document.

Changes and/or Comments:

The Office of Human Genome Research (HNAB), Office of the Director, NIH (HNA), has been converted to the National Center for Human Genome Research (NCHGR) (HN4). The functional statement is attached.

6. REORGANIZED COMPONENTS PLEASE NOTE: You are required to initiate action with your servicing Personnel Office. You must assure that all employees who are assigned to organizational components whose Standard Administrative Codes have been changed as a result of this organization change are appropriately reassigned.

7. DISTRIBUTION has been made to listees marked in red below.
You may determine from the list below which offices may have a need or interest in receiving a copy. However, you must send a copy to the offices already checked.

	X BID Directors/Executive Officers
Director, NIH	X Director, Division of Management Survey & Review
X Deputy Director, NIH	X Chief, Systems & Actions Branch, DPM (3)
X Deputy Director for Intramural Research	X Chief, Compensation & Classification Branch, DPM (2)
X Deputy Director for Extramural Research	X BID Personnel Office (2)
X Associate Director for Intramural Affairs	X BID Organizational Change Coordinator
X Associate Director for Extramural Affairs	X BID Budget Office
X Associate Director for Research Services	X Director, Division of Space Management, ORS
X Associate Director for Science Policy & Legislation	X Director, Division of Management Policy
X Associate Director for Administration	X Associate Director for AIDS Research
X Associate Director for Communications	X Associate Director for Human Genome Researc
X Director, Division of Technical Services, ORS	X Associate Director for Disease Prevention
X Director, Division of Contracts & Grants	X Associate Director for Scientific Integrity
X Director, Division of Financial Management	X Associate Director for Minority Programs
X Director, Division of Personnel Management	X Associate Director for International Researc

8. Signature

Cathy C. Hix

Cathy C. Hix, Chief, Managment Analysis Branch, DMP/OA

9. Date

October 4, 1989

NATIONAL CENTER FOR HUMAN GENOME RESEARCH (HN4)

(1) Advises the Director, NIH, and senior staff on all aspects of genomic analysis; (2) coordinates the integration, review, and planning of genomic analysis research; (3) formulates research goals and long-range plans with the guidance of the NIH Program Advisory Committee on Complex Genomes; (4) serves as a focal point for coordination within NIH and will be the DHHS point of contact for Federal interagency coordination, collaboration with industry and academia, and international cooperation; (5) fosters, conducts, supports, and administers research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes through: (a) research grants, contracts, and cooperative agreements to institutions and individuals; (b) individual and institutional research training awards; (c) promotion of closer interaction with other bases of genomic analysis research; and (d) collection and dissemination of research findings in these areas; (6) develops plans for the centralized, systematic, targeted effort to create detailed maps of the genomes of organisms; (7) establishes research goals and criteria for review or progress in meeting those goals; (8) sponsors scientific meetings and symposia to promote progress through information sharing; and (9) fosters national and international information exchange with industry and academia concerning research on complex genomes.

Effective: October 1, 1989

Public Health Service

National Institutes of Health; Statement of Organization, Functions and Delegations of Authority; Correction

Correction Noce. Part H. Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 54 FR 28495, July 6, 1989), is amended to restate Item 4 in the functional statement for the National Center for Human Genome Research (HN4) (54 FR 28495, July 6, 1989).

Section HN-B, Organization and Functions as amended as follows:

Under the heading National Center for Human Genome Research (HN4), delete Item 4 of the functional statement in its entirety and substitute the following: "(4) serves as a focal point for coordination within NIH and will be the DHHS point of contact for Federal interagency coordination, collaboration with industry and academia, and international cooperation."

Dated: August 28, 1989.

James E. Larson,

Acting Deputy Assistant Secretary for Information and Recources Management.

[FR Doc. 89-21673 Filed 9-14-89; 8:45 am]

BILLING CODE 4140-01-M

Family Support Administration

Forms submitted to the Office of Management and Budget for Clearance

The Family Support Administration (FSA) will publish on Fridays information collection packages submitted to the Office of Management and Budget (OMB) for clearance, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). Following is the package submitted to OMB since the last publication on September 9, 1989.

(Call the Reports Clearance Officer on 202-252-5604 for a copy of package)

Integrated Review Schedule—FSA 4357—0970-0035—State agencies are required to perform quality control reviews for each of the three federal assistance programs: AFDC, FNS and Medicaid. The Integrated Review Schedule is jointly designed and used by FSA, FNS and HCFA. The review schedule serves as the comprehensive data entry form for all quality control reviews in the AFDC, FNS and Medicaid programs. Respondents: State or local governments; Number of Respondents: 52,662; Frequency of Response: 1; Average Burden per Response: 1; Estimated Annual Burden: 52,662 hours.

OMB Desk Clearance Officer: Justin Kopca

Consideration will be given to comments and suggestions received within 60 days of publication. Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3201, 725 17th Street N.W., Washington, DC 20503.

Dated: September 8, 1989.

Sylvia E. Vela,

Deputy Associate Administrator, Office of Management and Information Systems.

[FR Doc. 89-21671 Filed 9-14-89; 8:45 am]

BILLING CODE 4150-04-M

Food and Drug Administration

[Docket No. 89E-0310]

Determination of Regulatory Review Period for Purposes of Patent Extension; Anionic Polyurethane

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Anionic Polyurethane and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims Anionic Polyurethane.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: I. David Wolfson, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Price Drug Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For food and color additives:

(1) The testing phase begins on the date a major health or environmental effects test is begun and ends on the date a petition relying on the test and requesting the issuance of a regulation for use of the additive under sections 409 (21 U.S.C. 348) or 706 (21 U.S.C. 376) of the Federal Food, Drug, and Cosmetic Act (the act) is initially submitted to FDA. An "environmental effects" test may be any test which: (i) Is reasonably related to the evaluation of the product's health effects, environmental effects, or both; (ii) produces data necessary for marketing approval; and (iii) is conducted over a period of not less than 6 month's duration, excluding time required to analyze or evaluate test results. 21 CFR 60.22(b)(1).

(2) The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 or 706 of the act is initially submitted to FDA and ends upon whichever of the following occurs last: (i) The regulation for the additive becomes effective; or (ii) objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted; or (iii) proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted. 21 CFR 60.22(b)(2). Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a color or food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA recently issued a regulation listing Anionic Polyurethane as an indirect food additive. Anionic

The Board of Governors of the Federal Reserve System, June 29, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-15824 Filed 7-5-89; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health; Statement of Organization, Functions and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1974, as amended most recently at 54 FR 5682, February 6, 1989), is amended to reflect the following changes within the National Institutes of Health effective October 1, 1989: (1) Abolish the Office of Human Genome Research (HNAB) within the Office of the Director, NIH; and (2) establish the National Center for Human Genome Research (HN4). These changes will more properly reflect the high priority placed on mapping and sequencing complex genomes and the expansion of the genome research effort.

Section HN-B, Organization and Functions, is amended as follows effective October 1, 1989:

(1) Under the heading *Office of the Director (HNA),* delete the title and statement for the *Office of Human Genome Research (HNAB)* in their entirety.

(2) After the statement for the *Clinical Center (HNJ),* insert the following:

National Center for Human Genome Research (HN4). (1) Advises the Director, NIH, and senior staff on all aspects of genomic analysis; (2) coordinates the integration, review, and planning of genomic analysis research; (3) formulates research goals and long-range plans with the guidance of the NIH Program Advisory Committee on Complex Genomes; (4) serves as a focal point on genomic analysis research within NIH, other components of the Public Health Service, and other Federal agencies (e.g., DOE and NSF); (5) fosters, conducts, supports, and administers research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes through: (a) Research grants, contracts, and cooperative agreements to institutions and individuals; (b) individual and institutional research training awards; (c) promotion of closer interaction with other bases of genomic analysis research; and (d) collection and dissemination of research findings in these areas; (6) develops plans for the centralized, systematic, targeted effort to create detailed maps of the genomes of organisms; (7) establishes research goals and criteria for review or progress in meeting those goals; (8) sponsors scientific meetings and symposia to promote progress through information sharing; and (9) fosters national and international information exchange with industry and academia concerning research on complex genomes.

This reorganization is effective October 1, 1989.

Date: June 22, 1989.

Louis W. Sullivan,

Secretary.

[FR Doc. 89-15787 Filed 7-5-89; 8:45 am]

BILLING CODE 4140-01-M

Centers for Disease Control

Human Neurobehavioral Effects of Combination Chemical Exposures; Meeting Change

This notice announces a change in the telephone number for the contact person for a previously announced meeting.

Federal Register Citation of Previous Announcement: 54 FR 24595, June 8, 1989.

Previously Announced Date and Time of the Meeting: July 7, 1989 9:00 a.m.-5:00 p.m.

Previously Announced Telephone Number: Commercial: (513) 553-8383

Change in the Telephone Number: Commerical: (513) 553-8383

Dated: June 26, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89-15817 Filed 7-5-89; 8:45am]

BILLING CODE 4160-19-M

Food and Drug Administration

[Docket No. 88N-0097]

Revised Chapter in Regulatory Procedures Manual; Perishable Foods Sampled by the Food and Drug Administration; Reannouncement of Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reannouncing availability of revised Regulatory Procedures Manual (RPM) Chapter 9-73, previously titled "Perishable Foods, Including Fresh Fish and Seafood and Fresh Produce." It is now titled "Perishable Foods Sampled by the Food and Drug Administration." The availability of the RPM Chapter was previously announced, but implementation was subsequently postponed until further notice because of concerns about the impact of these revised procedures. The revised chapter 9-73 now available continues to provide FDA districts with guidance for uniform handling of sampled imported perishable food but has been modified to reflect recent court decisions affecting all types of guidance issued by the agency. The title has also been changed to distinguish between the past and the current version of the document.

EFFECTIVE DATE: Revised RPM Chapter 9-73 will be effective on September 5, 1989.

ADDRESSES: Submit written requests for single copies of Regulatory Procedures Manual Chapter 9-73 "Perishable Foods Sampled by the Food and Drug Administration" to: Office of Regulatory Affairs, Import Operations Branch (HFC-131), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6553. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist in processing your request. Regulatory Procedures Manual Chapter 9-73 "Perishable Food Sampled by the Food and Drug Administration" is available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857-1706, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Marvin Blumberg, Office of Regulatory Affairs (HFC-131), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6553.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 29, 1988 (53 FR 28699), FDA announced the availability of revised Regulatory Procedures Manual Chapter 9-73. However, because of concerns about the impact of these revised procedures, in the Federal Register of November 4, 1988 (53 FR 44671), FDA announced that the effective date of the revised chapter had been delayed until further notice.

FDA is again announcing the availability of revised Chapter 9-73. The

4140-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

NATIONAL INSTITUTES OF HEALTH

Correction Notice

Statement of Organization, Functions and

Delegations of Authority

Correction Notice. Part H. Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 54 FR 28495, July 6, 1989), is amended to restate Item 4 in the functional statement for the National Center for Human Genome Research (HN4) (54 FR 28495, July 6, 1989).

Section HN-B, Organization and Functions is amended as follows:

Under the heading National Center for Human Genome Research (HN4), delete Item 4 of the functional statement in its entirety and substitute the following:

"(4) serves as a focal point for coordination within NIH and will be the DHHS point of contact for Federal interagency coordination, collaboration with industry and academia, and international cooperation."

8/28/89
Date

James E. Larson
Acting Deputy Assistant
Secretary for Information
and Resources Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 21 1989

Associate Director for Administration

Proposed Conversion of the Office of Human Genome Research to the National Center for Human Genome Research

James B. Wyngaarden, M.D.
Director, NIH

Attached is the organizational change proposal to convert the Office of Human Genome Research (OHGR) (HNAB) in the Office of the Director, NIH, to the National Center for Human Genome Research (HN4) effective October 1, 1989. This reorganization is in recognition of the high priority placed on mapping and sequencing the human genome and the substantial funding proposed for this program in the FY 1990 President's Budget.

The FY 1989 OHGR staffing will be increased from its current level of five (including one SES) positions to 23. This staffing increase will be accomplished within the current NIH ceiling. Effective October 1, 1989, the present OHGR staff (including the SES position) will be transferred to the new Center, and augmented with the remaining needed positions from within the FY 1990 budget.

The FY 1989 budget level is $27.6 million and the FY 1990 President's Budget request includes $100 million for funding the Human Genome Initiative. These funds have been included in the budget requests for the National Institute of General Medical Sciences ($99,088,000) and the Office of the Director ($912,000). It is expected that a separate appropriation will be requested for the new Center in FY 1991.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
MAB	Twelman	2/17/89						
DMP	Aarli	2/17/89						

The package has been reviewed by the Directors of the Divisions of Financial Management, Personnel Management, and Management Policy. You may indicate your concurrence by signing the attached memorandum to the Assistant Secretary for Health.

/s/ John D. Mahoney

John D. Mahoney

Attachments
Memorandum to the Assistant Secretary for Health from the Director, NIH
Memorandum to the Assistant Secretary for Management and Budget from the Assistant Secretary for Health
Federal Register notice
Organization charts

DMP:MAB:ETWILLMAN:et:1/18/89:revised:2/14/89
Official file located in DMP:MAB:496-2461

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date FEB 23 1989

From Director, NIH

Subject Proposed Organizational Change in the National Institutes of Health - ACTION

To Robert E. Windom, M.D.
Assistant Secretary for Health

ISSUE

Attached for your concurrence is a proposal to convert the Office of Human Genome Research (HNAB) in the Office of the Director (OD), NIH, to the National Center for Human Genome Research (HN4) effective October 1, 1989. This reorganization is in recognition of the high priority placed on mapping and sequencing the human genome and the substantial funding for this program proposed in the FY 1990 President's Budget.

DISCUSSION

On April 18, 1988, you approved our request to establish the Office of Human Genome Research (OHGR) within the OD/NIH with a staffing level of five positions. At that time NIH had a budget of $17 million for human genome research and was proposing a budget of $27.6 million for FY 1989. Under the current arrangement, OHGR activities have been primarily focused on planning and coordinating functions for the genome project and establishment of the NIH Program Advisory Committee on the Human Genome. Responsibility for administering grants and contracts funded with genome dollars has been with the National Institute of General Medical Sciences (NIGMS).

At the time of our initial request, we indicated our intention to establish the National Center for Human Genome Research (NCHGR) as a second-echelon line component of the NIH with its own research budget and grant-dispensing mechanisms, once the funding level for this activity increased. The prospect of a budget of $100 million for genome research in FY 1990 signals the need to move forward with the proposal to convert the OHGR to a Center effective October 1, 1989.

The Center will assume responsibility for all funds appropriated for the Human Genome program at NIH and will develop a broad research program on complex genomes that is a centrally planned, systematic, targeted effort to create detailed maps of the genomes of several organisms. Technology development, utilizing a variety of extramural grant and contract mechanisms and, possibly, intramural research, will be a major focus in the effort to develop a broad research program on complex genomes. Research goals and long-range plans will be formulated with the guidance of the NIH Program Advisory Committee on the Human Genome.

The Center will continue to perform the functions provided by the current OHGR (coordination, integration, planning, and progress review). Given the broad involvement by a number of Federal agencies and other funding organizations in research related to the characterization of complex genomes, coordination activities will be given added emphasis. The new Center will be the focal point for coordination within NIH, and will be the DHHS point of contact for Federal interagency coordination, collaboration with industry and academia, and international cooperation.

Specifically, the Center will be responsible for all planning and coordinating functions for the genome project, some of which are currently carried out by the BIDs. The establishment of the Center, however, will not have the effect of intruding upon existing interests of other BIDs. Rather, by supporting the development of general genome-related information and materials, the Center's activities will support and encourage the genetics activities of the categorical institutes. For example, there will continue to be a very close relationship between the research interests of the Center and the research interests of NIGMS, particularly the Genetics program. The close relationship in areas of interest between the Center and NIGMS represents an opportunity for synergism and mutual progress.

Center staff and the NIH Program Advisory Committee on the Human Genome will develop new initiatives, as well as recommend establishment of working groups and other activities requiring intense staff support. Initial efforts will include the establishment of genome research centers, a research training program, and new resources, and the improvement and expansion of existing resources. Relative to data base projects in molecular biology planned or underway within NIH components (Division of Research Resources, National Library of Medicine, and the National Institute of General Medical Sciences), the Center will provide leadership in the development of a trans-NIH plan for Genome Research and Biotechnology Information Systems.

While the NIH has traditionally taken the position opposing the establishment of new categorical organizations in response to emerging health problems, we have endorsed the creation of organizational entities when the conclusion was reached that they were needed. For example, the Division of Environmental Health Sciences was elevated to the National Institute of Environmental Health Sciences when it was determined that the health research programs of the Division had developed to a level requiring Institute status. Too often new organizations are promoted to focus attention on, and gain additional resources for a particular disease. This is clearly not the issue in this instance in that the Administration has already acknowledged the importance of this initiative and has committed itself to increasing resources in the FY 1990 budget.

Transition from Office to Center - The expansion of existing functions and the assumption of new duties requires that the current FY 1989 OHGR staffing level be increased from five to 23 positions and that some overhead functions, such as personnel and other administrative services, be shared. This expansion of staff is necessary if the Center is to assume full responsibility for managing a program of $100 million in FY 1990.

IMPACT

As stated above, the FY 1989 OHGR staffing will be increased from its current level of five (including one SES) positions to 23. This staffing increase will be accomplished within the current NIH FTE ceiling. Effective October 1, the OHGR staff (including the SES position) will be transferred to the new Center, and augmented with the remaining needed positions from within the FY 1990 budget. There will be no adverse personnel impact on involved employees, nor on NIH's EEO objectives.

The FY 1989 budget is approximately $27 million and the FY 1990 President's Budget request includes $100 million for funding the Human Genome Initiative. These funds have been included in the budget requests for the National Institute of General Medical Sciences ($99,088,000) and the Office of the Director ($912,000). Since the genome set-aside is a line item in the NIGMS budget, transfer of these funds will not affect other NIGMS programs. It is expected that a separate appropriation will be requested for the new Center in FY 1991.

RECOMMENDATION

I recommend that you indicate your concurrence with this organizational change by signing the attached memorandum to the Assistant Secretary for Management and Budget.

James B. Wyngaarden

James B. Wyngaarden, M.D.

Attachments
Memorandum to the Assistant Secretary for Management and Budget
from the Assistant Secretary for Health
Federal Register notice
Organization charts

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 23 1989

Acting Assistant Secretary for Health

Proposed Organizational Change in the National Institutes of Health - ACTION

Anthony S. McCann
Assistant Secretary for Management and Budget

ISSUE

Attached for your concurrence is a proposal to convert the Office of Human Genome Research (HNAB) in the Office of the Director (OD), NIH, to the National Center for Human Genome Research (HN4) effective October 1, 1989. The NIH is requesting an effective date of October 1, rather than the date of signature, because of the lead time needed to recruit additional resources so as to be fully operational as a Center when funds are available on October 1. This reorganization is in recognition of the high priority placed on mapping and sequencing the human genome and the substantial funding for this program proposed in the FY 1990 President's Budget.

BACKGROUND

On April 18, 1988, the request to establish the Office of Human Genome Research (OHGR) within the OD/NIH with a staffing level of five positions was approved. At that time NIH had a budget of $17 million for human genome research and was proposing a budget of $27.6 million for FY 1989. Under the current arrangement, OHGR activities have been primarily focused on planning and coordinating functions for the genome project and establishment of the NIH Program Advisory Committee on the Human Genome. Responsibility for administering grants and contracts funded with genome dollars has been with the National Institute of General Medical Sciences (NIGMS).

At the time of the initial request, NIH indicated its intention to establish the National Center for Human Genome Research (NCHGR) as a second-echelon line component of the NIH with its own research budget and grant-dispensing mechanisms, once the funding level for this activity increased.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
MAB	Twillman	3/15/89						
DHP	ABELL	3/15/89						

The prospect of a budget of $100 million for genome research in FY 1990 signaled the need to move forward with the proposal to convert the OHGR to a Center. Accordingly, in January, the Director, NIH, forwarded a concept paper to then Secretary Bowen requesting his approval of the need to effect the conversion of the OHGR to a National Center, given the anticipated FY 1990 increase in funding. Concerns raised during the OS staff review of the concept paper are addressed below.

Assistant Secretary for Management and Budget

Staffing

NIH is aware that there will be no additional staffing resources provided for this organizational change and that the administrative overhead needed to establish and manage the Center must come from within the overall resources allocated to NIH in FY 1989 and FY 1990. The proposed reorganization will be accomplished within the current NIH FTE ceiling.

Assistant Secretary for Planning and Evaluation

Formal Review

NIH appreciates the Assistant Secretary's interest in ensuring that a broad range of perspectives are heard regarding the merits of this proposal. However, should OS staff determine that a review outside the formal organizational change approval process is necessary, it is hoped that this review can be accomplished expeditiously.

Administrative Support

NIH is taking steps to ensure that the difficulties inherent in setting up a new Center do not divert scientific leadership now provided by the OHGR. Specifically, some overhead functions such as personnel and other administrative services will be shared during the transition phase from office to center.

Establishment of New Institutes

While the NIH has traditionally taken the position opposing the establishment of new categorical organizations in response to emerging health problems, it has endorsed the creation of organizational entities when the conclusion was reached that they were needed. For example, the Division of Environmental Health Sciences was elevated to the National Institute of Environmental Health Sciences when it was determined that the health research programs of the Division had developed to a level requiring Institute status. Too often new organizations are promoted to focus attention on, and gain additional resources for a particular disease. This is clearly not the issue in this

instance in that the Administration has already acknowledged the importance of this initiative and has committed itself to increasing resources in the FY 1990 budget.

Assistant Secretary for Legislation

Administrative/Research Center

The Center will continue to perform the functions provided by the current OHGR, and will assume responsibility for all funds appropriated for the human genome project at NIH. The National Center will be an administrative center in that it will not set up intramural laboratories; however, it may selectively provide extra funding to the intramural laboratories of other NIH components performing research relating to the Center's objectives in order to expedite such research.

Impact on Other NIH Genetics Research Projects

The Center will be responsible for all planning and coordinating functions for the human genome project. However, traditional human genetics research, both intramural and extramural, of other NIH components will continue to be managed by the categorical institutes and will be supported and encouraged through the Center's development and sharing of general genome-related information, materials, and technology.

Impact to the National Institute of General Medical Sciences (NIGMS)

There will continue to be a very close relationship between the research interests of the Center and the research interests of NIGMS, particularly the Genetics program. The close relationship in areas of interest between the Center and NIGMS represents an opportunity for synergism and mutual progress. FY 1990 funding for the Human Genome Initiative has been included in the NIGMS budget requests. Since the genome set-aside is a line item in the NIGMS budget, transfer of these funds will not affect other NIGMS programs.

DISCUSSION

The Center will assume responsibility for all funds appropriated for the human genome project at NIH and will develop a broad research program on complex genomes that is a centrally planned, systematic, targeted effort to create detailed maps of the genomes of several organisms. Technology development, utilizing a variety of extramural grant and contract mechanisms, will be a major focus in the effort to develop a broad research program

on complex genomes. Some incremental funding may also be made available, on a competitive basis, to existing intramural laboratories that choose to pursue research related to the objectives of the genome program. Research goals and long-range plans will be formulated with the guidance of the NIH Program Advisory Committee on the Human Genome.

The Center will continue to perform the functions provided by the current OHGR (coordination, integration, planning, and progress review). Given the broad involvement by a number of Federal agencies and other funding organizations in research related to the characterization of complex genomes, coordination activities will be given added emphasis. The new Center will be the focal point for coordination within NIH, and will be the DHHS point of contact for Federal interagency coordination, collaboration with industry and academia, and international cooperation.

Center staff and the NIH Program Advisory Committee on the Human Genome will develop new initiatives, as well as recommend establishment of working groups and other activities requiring intense staff support. Initial efforts will include the establishment of genome research centers, a research training program, and new resources, and the improvement and expansion of existing resources. Relative to data base projects in molecular biology planned or underway within NIH components (Division of Research Resources, National Library of Medicine, and the National Institute of General Medical Sciences), the Center will provide leadership in the development of a trans-NIH plan for Genome Research and Biotechnology Information Systems.

Transition from Office to Center - The expansion of existing functions and the assumption of new duties requires that the current FY 1989 OHGR staffing level be increased from five to 23 positions and that some overhead functions, such as personnel and other administrative services, be shared. This expansion of staff is necessary if the Center is to assume full responsibility for managing a program of $100 million in FY 1990.

IMPACT

As stated above, the FY 1989 OHGR staffing will be increased from its current level of five (including one SES) positions to 23. This staffing increase will be accomplished within the current NIH FTE ceiling. Effective October 1, the OHGR staff (including the SES position) will be transferred to the new Center, and augmented with the remaining needed positions from within the FY 1990 budget. There will be no adverse personnel impact on involved employees, nor on NIH's EEO objectives.

The FY 1989 budget is approximately $27 million and the FY 1990 President's Budget request includes $100 million for funding the Human Genome Initiative. These funds have been included in the budget requests for the National Institute of General Medical Sciences ($99,088,000) and the Office of the Director ($912,000). Since the genome set-aside is a line item in the NIGMS budget, transfer of these funds will not affect other NIGMS programs. It is expected that a separate appropriation will be requested for the new Center in FY 1991.

RECOMMENDATION

I recommend that the Secretary sign the attached Federal Register notice.

/s/

Ralph R. Reed, M.D.

Attachments
Federal Register notice
Organization charts

NIH:OA:DMP:MAB:ETWILLMAN:et:1/18/89:revised;2/16/89
revised:3/14/89
Official file located in DMP:MAB:496-2461

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assistant Secretary for Health

Proposed Organizational Change in the National Institutes of Health - ACTION

Anthony S. McCann
Assistant Secretary for Management and Budget

ISSUE

Attached for your concurrence is a proposal to convert the Office of Human Genome Research (HNAB) in the Office of the Director (OD), NIH, to the National Center for Human Genome Research (HN3) effective October 1, 1989. This reorganization is in recognition of the high priority placed on mapping and sequencing the human genome and the substantial funding for this program proposed in the FY 1990 President's Budget.

DISCUSSION

On April 18, 1988, the request to establish the Office of Human Genome Research (OHGR) within the OD/NIH with a staffing level of five positions was approved. At that time NIH had a budget of $17 million for human genome research and was proposing a budget of $27.6 million for FY 1989. Under the current arrangement, OHGR activities have been primarily focused on planning and coordinating functions for the genome project and establishment of the NIH Program Advisory Committee on the Human Genome. Responsibility for administering grants and contracts funded with genome dollars has been with the National Institute of General Medical Sciences (NIGMS).

At the time of the initial request, NIH indicated its intention to establish the National Center for Human Genome Research (NCHGR) as a second-echelon line component of the NIH with its own research budget and grant-dispensing mechanisms, once the funding level for this activity increased. The prospect of a budget of $100 million for genome research in FY 1990 signals the need to move forward with the proposal to convert the OHGR to a Center effective October 1, 1989.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HAB		2/15/89						
OMP		2/10/89						
NIGMS		2/15/89						

U.S. GPO 1986-169-089

While the NIH has shared the concerns of the Department regarding the establishment of new categorical organizations in response to emerging health problems, it has not opposed the creation of a new institute when the conclusion was reached that it was needed. For example, the Division of Environmental Health Sciences was elevated to the National Institute of Environmental Health Sciences when it was determined that the health research programs of the Division had developed to the point that the title of Institute was more appropriate.

The Center will continue to perform the functions provided by the current OHGR (coordination, integration, planning, and progress review). In addition, the Center will assume responsibility for all funds appropriated for the Human Genome program at NIH and will develop a broad research program on complex genomes that is a centrally planned, systematic, targeted effort to create detailed maps of the genomes of several organisms. Technology development, utilizing a variety of extramural grant and contract mechanisms and, possibly, intramural research, will be a major focus in the effort to develop a broad research program on complex genomes. Research goals and long-range plans will be formulated with the guidance of the NIH Program Advisory Committee on the Human Genome.

Given the broad involvement by a number of Federal agencies and other funding organizations in research related to the characterization of complex genomes, coordination activities will be given added emphasis. The new Center will be the focal point for coordination within NIH, and will be the DHHS point of contact for Federal interagency coordination, collaboration with industry and academia, and international cooperation.

Specifically, the Center will assume all planning and coordinating functions for the genome project, some of which are currently carried out by the BIDs. The establishment of the Center, however, will not have the effect of intruding upon existing interests of other BIDs. Rather, by supporting the development of general genome-related information and materials, the Center's activities will support and encourage the genetics activities of the categorical institutes. For example, there will continue to be a very close relationship between the research interests of the Center and the research interests of NIGMS, particularly the Genetics program. The close relationship in areas of interest between the Center and NIGMS represents an opportunity for synergism and mutual progress.

Center staff and the NIH Program Advisory Committee on the Human Genome will develop new initiatives, as well as recommend establishment of working groups and other activities requiring intense staff support. Initial efforts will include the establishment of genome research centers, a research training program, and new resources, and the improvement and expansion of existing resources. Relative to data base projects in molecular biology planned or underway within NIH components (Division of Research Resources, National Library of Medicine, and the National Institute of General Medical Sciences), the Center will provide leadership in the development of a trans-NIH plan for Genome Research and Biotechnology Information Systems.

Transition from Office to Center - The expansion of existing functions and the assumption of new duties requires that the current FY 1989 OHGR staffing level be increased from five to 23 positions, and that some overhead functions be shared. This expansion of staff is necessary if the Center is to assume full responsibility for managing a program of $100 million in FY 1990.

IMPACT

As stated above, the FY 1989 OHGR staffing will be increased from its current level of five (including one SES) positions to 23. This staffing increase will be accomplished within the current NIH FTE ceiling. Effective October 1, the OHGR staff (including the SES position) will be transferred to the new Center, and augmented with the addition of nine FTEs requested for FY 1990. There will be no adverse personnel impact on involved employees, nor on NIH's EEO objectives.

The FY 1989 budget is approximately $27 million and the FY 1990 President's Budget request includes $100 million for funding the Human Genome Initiative. These funds have been included in the budget requests for the National Institute of General Medical Sciences ($99,088,000) and the Office of the Director ($912,000). Since the genome set-aside is a line item in the NIGMS budget, transfer of these fund will not affect other NIGMS programs. It is expected that a separate appropriation will be requested for the new Center in FY 1991.

RECOMMENDATION

I recommend that the Secretary sign the attached Federal Register notice.

Robert E. Windom, M.D.

Attachments
Federal Register notice
Organization charts

NIH:OA:DMP:MAB:ETWILLMAN:et:1/18/89:revised;2/14/89
Official file located in DMP:MAB:496-2461

4140-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

NATIONAL INSTITUTES OF HEALTH

Statement of Organization, Functions and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 54 FR 5682, February 6, 1989), is amended to reflect the following changes within the National Institutes of Health effective October 1, 1989: (1) Abolish the Office of Human Genome Research (HNAB) within the Office of the Director, NIH; and (2) establish the National Center for Human Genome Research (HN4). These changes will more properly reflect the high priority placed on mapping and sequencing complex genomes and the expansion of the genome research effort.

Section HN-B, Organization and Functions, is amended as follows effective October 1, 1989:

(1) Under the heading Office of the Director (HNA), delete the title and statement for the Office of Human Genome Research (HNAB) in their entirety.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
NAB	Guillmin	2/15/89	DFM	Miller	2/17/89	D	Wyngaarden	2/23/89
OMP	NBEW	2/14/89	ADD	Stafford	2/17/89			
OGMS	PRKirschner	2/16/89	OHGR	Jordan	2/17/89			

U.S. GPO 1986-169-089

4140-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

NATIONAL INSTITUTES OF HEALTH

Statement of Organization, Functions and

Delegations of Authority

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(1) Under the heading Office of the Director (HNA), delete the title and statement for the Office of Human Genome Research (HNAB) in their entirety

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

(2) After the statement for the Clinical Center (HNJ), insert the following:

National Center for Human Genome Research (HN4). (1) Advises the Director, NIH, and senior staff on all aspects of genomic analysis; (2) coordinates the integration, review, and planning of genomic analysis research; (3) formulates research goals and long-range plans with the guidance of the NIH Program Advisory Committee on Complex Genomes; (4) serves as a focal point on genomic analysis research within NIH, other components of the Public Health Service, and other Federal agencies (e.g., DOE and NSF); (5) fosters, conducts, supports, and administers research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes through: (a) research grants, contracts, and cooperative agreements to institutions and individuals; (b) individual and institutional research training awards; (c) promotion of closer interaction with other bases of genomic analysis research; and (d) collection and dissemination of research findings in these areas; (6) develops plans for the centralized, systematic, targeted effort to create detailed maps of the genomes of organisms; (7) establishes research goals and criteria for review or progress in meeting those goals; (8) sponsors scientific meetings and symposia to promote progress

through information sharing; and (9) fosters national and international information exchange with industry and academia concerning research on complex genomes.

JUN 22 1989
Date

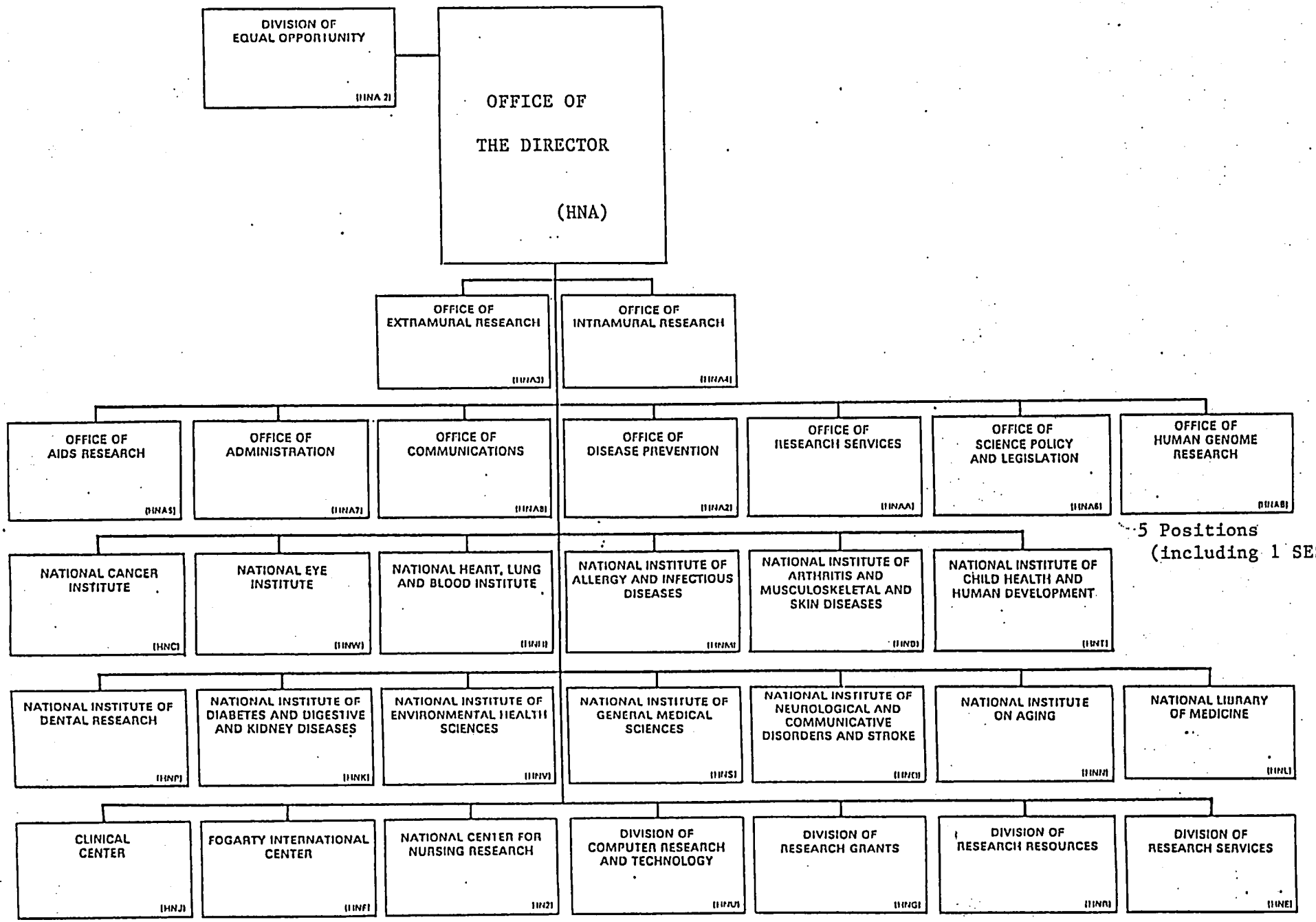
/s/
Louis W. Sullivan, M.D.
Secretary

NIH:OD:OA:DMO:MAB:ETWILLMAN:et:1/17/89:revised:2/14/89
Official file located in DMP:MAB:496-2461

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PRESENT

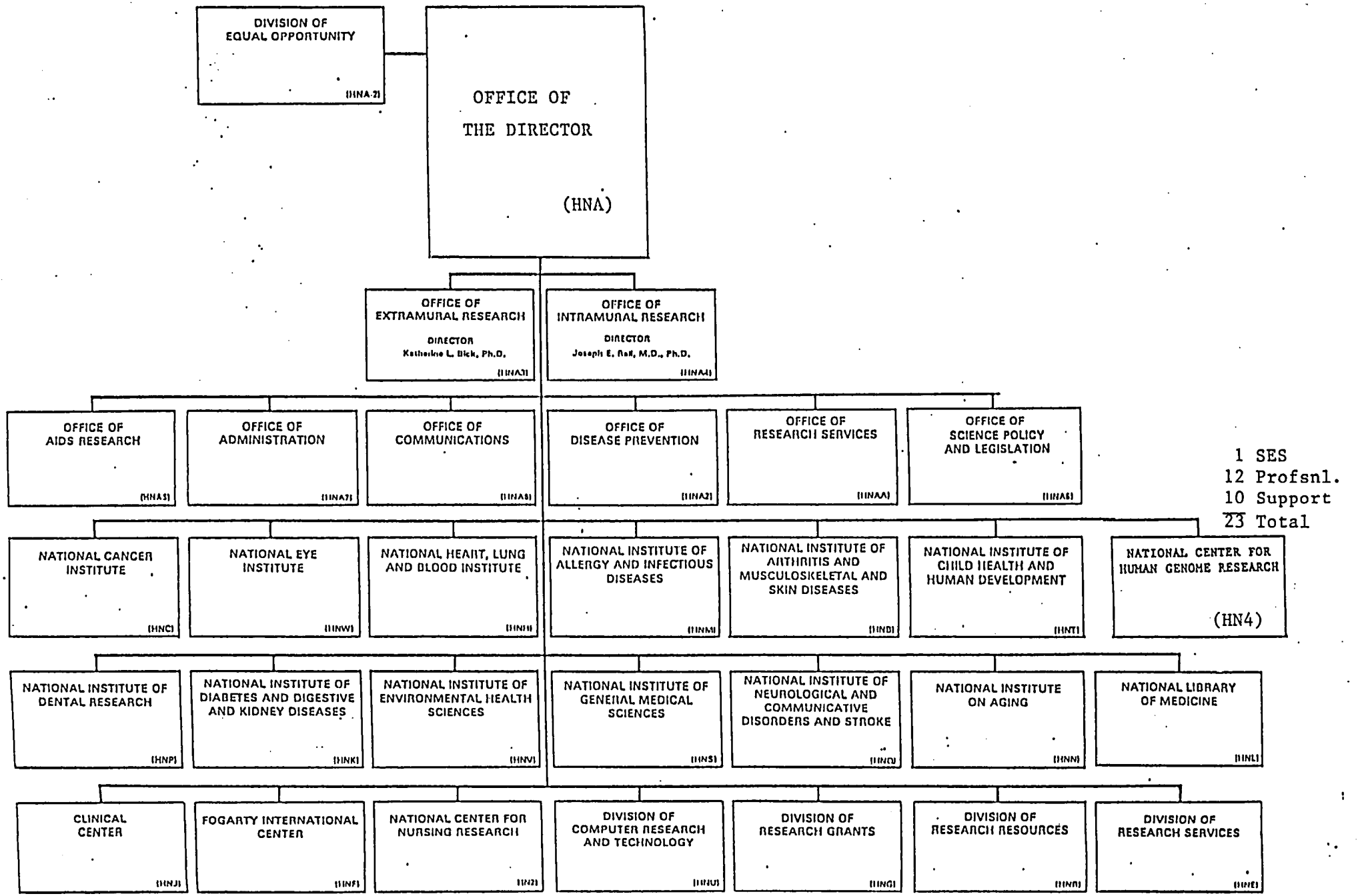
Public Health Service
National Institutes of Health



DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROPOSED

Public Health Service
National Institutes of Health



1 SES
12 Profsnl.
10 Support
23 Total

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health; Statement of Organization, Functions and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1974, as amended most recently at 54 FR 5682, February 6, 1989), is amended to reflect the following changes within the National Institutes of Health effective October 1, 1989: (1) Abolish the Office of Human Genome Research (HNAB) within the Office of the Director, NIH; and (2) establish the National Center for Human Genome Research (HN4). These changes will more properly reflect the high priority placed on mapping and sequencing complex genomes and the expansion of the genome research effort.

Section HN–B, Organization and Functions, is amended as follows effective October 1, 1989:

(1) Under the heading *Office of the Director (HNA),* delete the title and statement for the *Office of Human Genome Research (HNAB)* in their entirety.

(2) After the statement for the *Clinical Center (HNJ),* insert the following:

National Center for Human Genome Research (HN4). (1) Advises the Director, NIH, and senior staff on all aspects of genomic analysis; (2) coordinates the integration, review, and planning of genomic analysis research; (3) formulates research goals and long-range plans with the guidance of the NIH Program Advisory Committee on Complex Genomes; (4) serves as a focal point on genomic analysis research within NIH, other components of the Public Health Service, and other Federal agencies (e.g., DOE and NSF); (5) fosters, conducts, supports, and administers research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes through: (a) Research grants, contracts, and cooperative agreements to institutions and individuals; (b) individual and institutional research training awards; (c) promotion of closer interaction with other bases of genomic analysis research; and (d) collection and dissemination of research findings in these areas; (6) develops plans for the centralized, systematic, targeted effort to create detailed maps of the genomes of organisms; (7) establishes research goals and criteria for review or progress in meeting those goals; (8) sponsors scientific meetings and symposia to promote progress through information sharing; and (9) fosters national and international information exchange with industry and academia concerning research on complex genomes.

This reorganization is effective October 1, 1989.

Date: June 22, 1989.

Louis W. Sullivan,

Secretary.

[FR Doc. 89–15787 Filed 7–5–89; 8:45 am]

BILLING CODE 4140–01–M

Centers for Disease Control

Human Neurobehavioral Effects of Combination Chemical Exposures; Meeting Change

This notice announces a change in the telephone number for the contact person for a previously announced meeting.

Federal Register Citation of Previous Announcement: 54 FR 24595, June 8, 1989.

Previously Announced Date and Time of the Meeting: July 7, 1989 9:00 a.m.–5:00 p.m.

Previously Announced Telephone Number: Commercial: (513) 553–6383

Change in the Telephone Number: Commerical: (513) 553–6383

Dated: June 26, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89–15617 Filed 7–5–89; 8:45am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 88N–0097]

Revised Chapter in Regulatory Procedures Manual; Perishable Foods Sampled by the Food and Drug Administration; Reannouncement of Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reannouncing availability of revised Regulatory Procedures Manual (RPM) Chapter 9–73, previously titled "Perishable Foods, Including Fresh Fish and Seafood and Fresh Produce." It is now titled "Perishable Foods Sampled by the Food and Drug Administration." The availability of the RPM Chapter was previously announced, but implementation was subsequently postponed until further notice because of concerns about the impact of these revised procedures. The revised chapter 9–73 now available continues to provide FDA districts with guidance for uniform handling of sampled imported perishable food but has been modified to reflect recent court decisions affecting all types of guidance issued by the agency. The title has also been changed to distinguish between the past and the current version of the document.

EFFECTIVE DATE: Revised RPM Chapter 9–73 will be effective on September 5, 1989.

ADDRESSES: Submit written requests for single copies of Regulatory Procedures Manual Chapter 9–73 "Perishable Foods Sampled by the Food and Drug Administration" to: Office of Regulatory Affairs, Import Operations Branch (HFC–131), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist in processing your request. Regulatory Procedures Manual Chapter 9–73 "Perishable Food Sampled by the Food and Drug Administration" is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857–1706, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Marvin Blumberg, Office of Regulatory Affairs (HFC–131), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 29, 1988 (53 FR 28699), FDA announced the availability of revised Regulatory Procedures Manual Chapter 9–73. However, because of concerns about the impact of these revised procedures, in the Federal Register of November 4, 1988 (53 FR 44671), FDA announced that the effective date of the revised chapter had been delayed until further notice.

FDA is again announcing the availability of revised Chapter 9–73. The

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

ADA 3/13/89

Date MAR 10 1989

To: Dr. Jordan
Dr. Moskowitz
Ms. Barros

From Deputy Assistant Secretary for Health
(Planning and Evaluation)

Subject Proposed Establishment of National Center for Human Genome Research at NIH

To Deputy Assistant Secretary for Health Operations

The Department reviewed the NIH proposal to establish the National Center for Human Genome Research as a concept in January (see Attachments).

Dr. Windom sent a note to Dr. Wyngaarden on January 17 forwarding the OS comments and concerns and asking that NIH respond. The organizational change proposal that you sent me for review does not provide the detailed analysis needed to address the important questions posed by reviewers of the concept proposal.

Therefore, I cannot recommend that this formal proposal to establish the National Center for Human Genome Research be forwarded to the Secretary until the issues raised by OS are addressed.

Steven A. Grossman

Attachments

NIH-OD-OA

89 MAR 13 P3:24

OHGR

Office of the Director
Office of Human Genome Research

	FY 1989 Budget FTEs	FY 1989 Budget Dollars	FY 1989 Current Estimate FTEs	FY 1989 Current Estimate Dollars	FY 1990 Request Level 1/ (Per C.J.) FTEs	FY 1990 Request Level 1/ (Per C.J.) Dollars	FY 1990 Current Estimate FTEs	FY 1990 Current Estimate Dollars
Personal Services:	5	233		460	12	$610 2/	28	1,283
Other:								
Travel		45		45		30		~~60~~ 80
Printing		2		2		10		5
Other Services		105		162		177		~~295~~ 375
Advisory Comm/Workshops		(90)		(141)		(133) 3/		~~(230)~~ (330)
Other		(15)		(21)		(44)		(65)
Supplies & Materials		5		5		10		15
Equipment		10		165		75		230
Subtotal, Other						302		605
Total		$489		$839		$912		$1,888

NOTE: The current estimates for 1989 and 1990 assume that the office will be converted to a Center.

1/ Assumes that grants management and contract support functions will remain in the BIDs that are currently funding these activities. These functions will be transferred to the HGRC in subsequent fiscal years.
2/ Excludes 2 FTEs for Personnel & Budget support functions. (Estimated cost is $100K)
3/ Twelve member advisory committee for 3 meetings plus support and subcommittee meetings.

Background:
The OHGR was established on April 18, 1988, by the Assistant Secretary for Health to recognize the high priority placed on mapping and sequencing complex genomes. OHGR provides coordination, integration, planning and progress reviews on genomic analysis research. OHGR provides a focus within DHHS for review of policy questions, coordination of future research efforts, and the exchange of information relative to scientific activities in the Intramural Research Program.

Accomplishments: Recent accomplishments include:
- o Appointment of Nobel Laureate James Watson as Associate Director for Human Genome Research.
- o Appointment of Director of the Office (Dr. Elke Jordon).
- o Establishment of the NIH Program Advisory Committee on the Human Genome.
- o Coordination established with the National Science Foundation (NSF), U.S. Dept. of Agriculture (USDA), and the Howard Hughes Medical Institute (HHMI). Dept of Energy (DOE) the added

FY 1989 Plans: The OGHR will continue to implement the staffing plan for the office. OGHR will operate with an initial staff of 5 (3 FTEs). Management of contracts under the Human Genome program will continue to be provided by the National Institute of General Medical Sciences. The NIH Program Advisory Committee on the Human Genome is expected to meet twice this fiscal year to develop a number of new initiatives.

FY 1990 Plans: The President's Budget provides 12 FTEs and approximately $912,000 for the OGHR. NIGMS will continue to manage contracts and grants for the Human Genome program. OGHR will continue to implement a Memorandum of Understanding between NIH and the Department of Energy that specifies a mechanism for congruent advice being provided to the two agencies on the Human Genome Mapping effort. Continued coordination of the mapping effort with other agencies and groups remains a high priority. Several workshops and initiatives are planned, some in collaboration with DOE and HHMI.

* Conversation to a Center: Dr. Wyngaarden has proposed that the NIH Office of Human Genome Research be converted to an independent center for human genome research. He cited the highly specialized approaches to the human genome research effort and the rapid rate of growth of the budget for genome research in recommending the conversion of a staff office to an independent operating unit, with its own authority to review and award grants with advice from its own National Advisory Council.

* Needs Revision/Expansion A proposal has been forwarded to the department of HHS.

OHGR

FEB 03 1989

NOTE TO MR. MAHONEY

Subject: Recruitment Times for OHGR

Colleen asked that I give you some impression of the time frames required for recruitment actions within OHGR. On Monday, Pat and I discussed these times and the types of recruitment with Elke. I suggested that she might wish to consider a number of different appointment mechanisms for staffing OHGR, making use of quick appointment methods for her short term needs and using the more time consuming methods for longer term goals. In addition, we discussed using MIs or PMIs on assignment. In any event, Elke was given the following information:

1. Special Experts are easily and quickly appointed. Once a candidate is identified, the paperwork takes less than a month to complete, including arranging an EOD date. Even advertising an expert position would create only a short delay of about one month. I warned Elke that the conversion of an expert is problematic and time consuming (about 6 months). Experts should be used for professional positions at the GS-13 or above range and have maximum appointment periods of four years. Hiring an expert will require about two months, including advertisement.

2. Lateral reassignment of existing professional or clerical employees is perhaps the fastest method of hiring. If employees at NIH or other agencies can be identified and reassigned, the process will take less than two months.

3. Competitive reassignment requires local advertisement and, in most cases, a rating panel (competitive reassignments moving intramural scientists to Health Scientist Administrator positions require action by the NIH Board of Examiners). Three months is a reasonable time for the action to be completed.

4. New hires requiring the use of OPM registers will take the greatest time. The use of many registers will take a minimum of three months, excluding any necessary advertisement and interview period. Additional time will be required if we wish to appoint above the minimum level (step 1). Five months is the best estimate I can offer, although it may be somewhat longer.

5. Clerical recruitment, although it falls under the lateral reassignment or competitive reassignment category, requires further explanation. Because of the shortage of high quality clerical people, the time is often increased while we readvertise positions. I told Elke that she should consider starting recruitment for clericals as soon as possible, even though they might prefer to wait until professional staff members are hired.

All of the above time frames are based upon receipt of complete recruitment packages in the personnel office. This includes position description, evaluation criteria, SF-52 and any other necessary appointment

documentation. If we are required to write position descriptions, etc., the times will be longer.

I need to warn you that if we are to deal with this number of vacancies and give them priority consideration, we will need to shift staff from other areas. This will increase delays in processing day-to-day actions.

I have attached a copy of a listing of the projected positions within OHGR and listed the time frames I believe apply to each.

Fred

Fred Walker

cc: Ms. Barros

OFFICE OF HUMAN GENOME RESEARCH
STAFFING TIME FRAMES

POSITION	RECRUITMENT TYPE	TIME
FY 89		
Executive Officer	Competitive or lateral reassignment	2-3 months
Budget Officer	Competitive or lateral reassignment	2-3 months
Secretary (5 positions)	Competitive or lateral reassignment	2-3 months
Data Mgmt. Officer	New hire or reassignment	2-5 months
Grants Mgmt. Off.	Competitive or lateral reassignment	2-3 months
Grants Mgmt. Spec.	Competitive or lateral reassignment	2-3 months
Grants Tech. Asst. (3 positions)	Competitive or lateral reassignment	2-3 months
File Clerk	Competitive or lateral reassignment	2-3 months
Director, Extra.	Expert, new hire or reassignment	2-5 months
Health Sci. Adm./ Exec. Sec. (5 positions)	Expert, new hire, reassignment or Grants Associate	2-5 months

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : Shannon
Room : 102
(301) 496- 4466

FEB 10 1989

NOTE TO DR WYNGAARDEN

Subject: Establishment of a National Center for Human Genome Research

Jim:

In order to develop the formal organizational proposal to establish the National Center for Human Genome Research and to begin to plan for its development, we have taken several steps:

1. Dr. Jordan developed a proposed staffing plan outlining the number of people that will be required assuming that the Center will be fully operational in FY 1990. Her proposal which assumes that personnel and other administrative services, such as public affairs, EEO, and legislative affairs, will be provided by another BID is shown as Attachment A. This proposal identifies staff growth through three phases, the first of which calls for 23 people on board by October 1, 1989.

2. Dr. Jordan and I met with Dr. Kirschstein to get a better understanding of any flexibility in her desire to have the genome effort transferred to the new Center on October 1, 1989. There seemed to be a small element of flexibility in that she seemed agreeable to a January 1, 1990 transfer date, although she firmly wants to have the Center established as quickly as possible.

3. My staff has constructed a time line for the hiring of the additional 18 people and identifying space for this Center. It will take at least 5 months to hire these people after all of the position descriptions are written. (It probably would be wise to overallocate a position to the personnel office at least temporarily to accommodate this additional workload and avoid further diminution of services to the rest of OD.) Making projections on space time lines is more difficult. If space currently available in Executive Plaza were acceptable, there would be no time delay; if space on the NIH campus is required, the various moves could require seven months. There are compelling reasons for keeping the Center on campus because of extensive interaction with other NIH components.

4. A senior administrative officer needs to be hired to handle the myriad actions that have to be organized and completed including the development of the position descriptions for the anticipated staff. A person has been identified and references are being checked.

5. I have met with Dr. Watson to discuss the types of personnel appointments that will allow him to direct the Center. He was agreeable to becoming a Special Expert, although it will not allow us to pay his travel costs and will substantially reduce the amount that we are now paying him as a Regular Expert. This appointment mechanism is acceptable to Bill Forbush and we will now pursue it with Tom McFee. I also told Dr. Watson that Bob Lanman should once again review for conflict of interest since he would now have operational responsibilities.

If Does this mean that the OHGR will do his travel? ces policies

IMMEDIATE NEXT STEPS

Basically, the following decisions need to be made on the assumpt that we want to have a fully operational Center as early in FY 19: possible:

1. Level of Resources:

The level of resources (23 FTEs) proposed by Dr. Jordan seems appropriate if the Center is to assume full responsibility for managing a program of $100 million in FY 1990. This obviously is a higher level of resources than currently budgeted. The FY 1990 President's Budget had assumed a multi-year transition and requested a total of 12 FTEs and $1.5 million. The FTE allocations to other BIDs would have to be reduced to accommodate the additional 13 FTEs and support costs would need to be reallocated from within the genome budget. Accommodations will also have to be made in 1989 as most of the unbudgeted hiring will occur this year.

A decision on the level of resources is needed to complete the proposed organizational package.

2. Hiring of Staff, etc.

The preliminary estimates from my staff regarding hiring and space lead-times indicate that if we started a concerted effort and everything went smoothly, we might be fully operational by the end of the summer. However, since nothing ever goes smoothly, it is reasonable to assume that it will take at least another 3 months at a minimum. This assumes that we begin this undertaking now before there is Secretarial approval of the organizational package. Obviously, this strategy is appropriate only if we are absolutely confident of Secretarial approval; otherwise we will have hired staff that would have to be placed elsewhere.

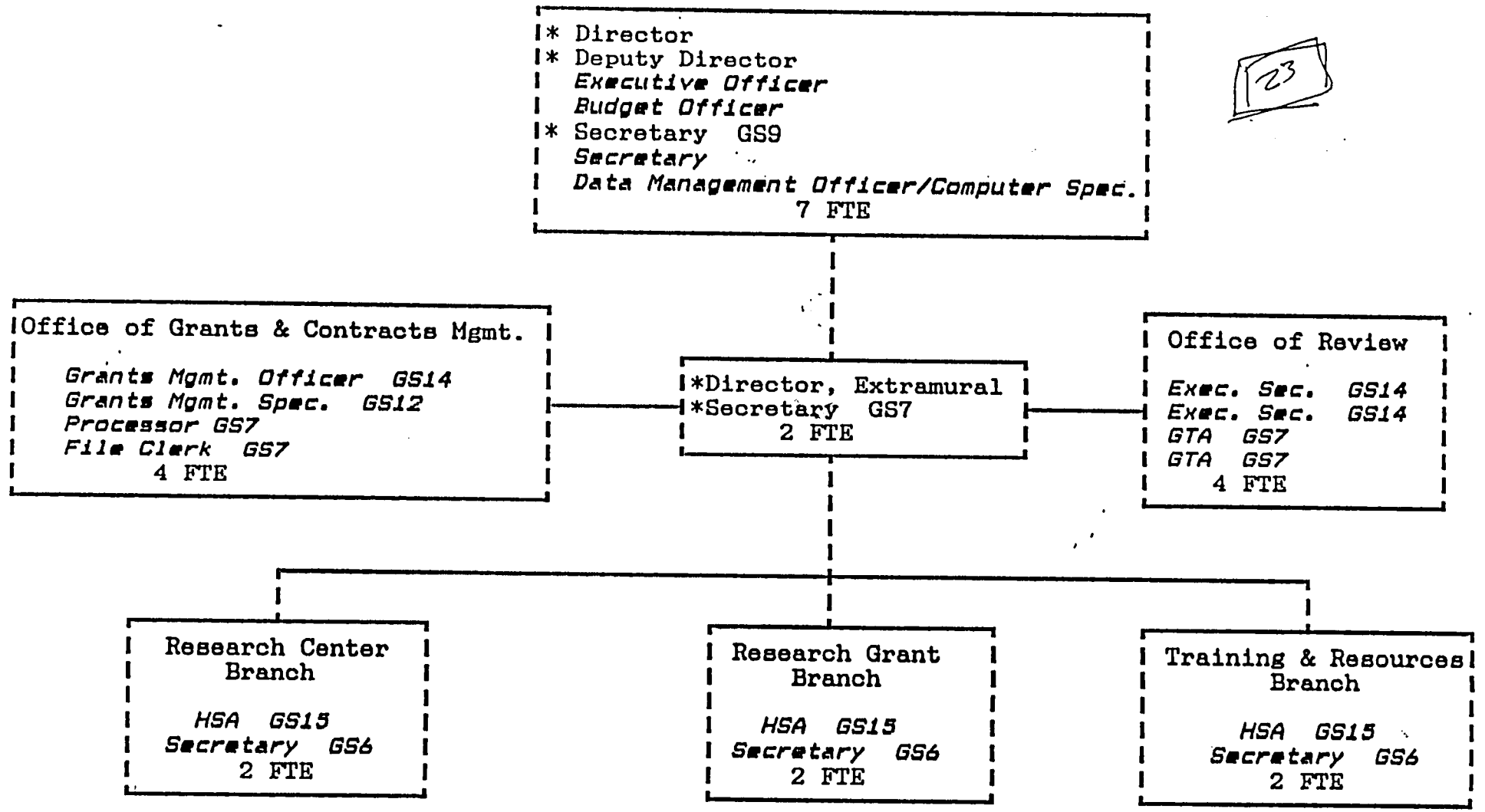
If we adopt a more cautious approach and begin a concerted effort after Secretarial approval, it will likely add another 2-3 months to the projected completion date.

Jack Mahoney

Attachment

OFFICE OF HUMAN GENOME RESEARCH

STAFFING NEEDED BY OCTOBER 1, 1989**



** Assume type 5's remain in GM, otherwise 3-4 extra FTE
* On board FY89

OFFICE OF HUMAN GENOME RESEARCH

STAFFING NEEDED BY END OF FY 1990

33

Director
Deputy Director
Executive Officer
Budget Officer
Secretary GS9
Secretary
Secretary
Committee Management Officer
Data Management Officer/Computer Spec.
9 FTE

Office of Grants & Contracts Mgmt.

Grants Mgmt. Officer GS14
Grants Mgmt. Spec. GS12
Processor GS7
Processor GS7
File Clerk GS7
File Clerk GS5
6 FTE

Director, Extramural
Program Analyst GS13
Secretary GS7
3 FTE

Office of Review

Exec. Sec. GS14
Exec. Sec. GS14
GTA GS7
GTA GS7
4 FTE

Research Center Branch

HSA GS15
HSA GS14
Secretary GS6
Secretary GS6
4 FTE

Research Grant Branch

HSA GS15
HSA GS14
Secretary GS6
Secretary GS6
4 FTE

Training & Resources Branch

HSA GS15
Program Analyst GS13
Secretary GS6
3 FTE

OFFICE OF HUMAN GENOME RESEARCH

FULL STAFFING

140

Director
Deputy Director
Executive Officer
Administrative Officer
Budget Officer
Secretary GS9
Secretary
Secretary
Committee Management Officer
Data Management Officer/Computer Spec.
10 FTE

Office of Grants & Contracts Mgmt.

Grants Mgmt. Officer GS14
Grants Mgmt. Spec. GS12
Processor GS7
Processor GS7
Contract Spec. GS7
Secretary GS7
File Clerk GS7
File Clerk GS5
8 FTE

Director, Extramural
Program Analyst GS13
Secretary GS7
3 FTE

Office of Review

Exec. Sec. GS14
Exec. Sec. GS14
GTA GS7
GTA GS7
4 FTE

Research Center Branch

HSA GS15
HSA GS14
Program Analyst GS13
Secretary GS6
Secretary GS6
5 FTE

Research Grant Branch

HSA GS15
HSA GS14
Program Analyst GS13
Secretary GS6
Secretary GS6
5 FTE

Training & Resources Branch

HSA GS15
HSA GS14
Program Analyst GS13
Secretary GS6
Secretary GS6
5 FTE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

JAN 17 1990

NOTE TO DR. WYNGAARDEN

Subject: NIH Concept Proposal of Establishment of Human Genome Research Center

The concept proposal to establish a center for Human Genome Research at NIH has been reviewed by the Office of the Secretary. Comments were received from the Assistant Secretaries for Legislation, Management and Budget, and Planning and Evaluation. As indicated in the attached notes, views ranged from concurrence with the concept to concerns about budgetary and resource constraints, the center approach, and the scarcity of details in the proposal.

Please respond to each of the issues and questions raised in the attached notes. Your response should be sent directly to me for review.

Robert E. Windom, M.D.
Assistant Secretary for Health

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MEMORANDUM TO EXECUTIVE SECRETARIAT

Attn: Michael Eck

From : S. Anthony McCann
Assistant Secretary for Management and Budget

Subject: Creation of a Center for Human Genome Research at NIH

I have no objection to the conversion of the current Office of Human Genome Research in the Office of the Director, NIH to an independent Center for Human Genome Research at NIH. As Dr. Wyngaarden's memorandum implies, the growing national and international attention to the concept of sequencing the entire human genome make coordination of this effort essential if we are to avoid duplication of effort and the wasting of precious resources.

NIH needs to clearly understand that there will be no additional resources, particularly staffing resources, provided for this organizational change and that the administrative overhead needed to establish and manage the Center will have to come from within the overall resources allocated to NIH in FY 1989 and FY 1990.

With the above caveat in mind, I have no objection to the proposed organization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

TO : Michael Eck
Executive Secretariat

FROM : Robert B. Helms, Ph.D.
Assistant Secretary for
Planning and Evaluation

SUBJECT: Concept of Establishing a Center for Human Genome Research -- CONCURRENCE WITH COMMENTS

I support Dr. Wyngaarden's goal to maximize the effectiveness of NIH leadership in human genome research. However, I have procedural and philosophical concerns regarding the January 4 memorandum.

I believe that the human genome project will be a major biomedical research initiative in the next decade, and that the long run budgetary impact of human genome research will be extraordinary. Therefore, the establishment of a separate center is a major policy decision ordinarily requiring a consideration of many alternatives. The Secretarial endorsement of a specific strategy should generally be made by means of the Policy Council or other formal mechanism which assures that a broad range of perspectives are heard.

I am skeptical that establishing a center is the optimal strategy in the near term. A new center will inevitably require administrative support that will be both hard to come by and take time to establish. I wonder if the difficulties inherent in setting up a new center under the current budgetary climate would dilute and divert scientific leadership now provided by the Office of Human Genome Research. I am also concerned about the possibility that a Secretarial endorsement of this center would play into the hands of those who argue that a new center or institute is necessary to gain visibility and support for other special programs. This Department has consistently opposed the policy of establishing new NIH organizations to respond to emerging problems (e.g., nursing, deafness, and arthritis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

JAN 13 '88

NOTE TO MICHAEL ECK

While we do not disagree with the concept of a humane genome center at NIH, we nevertheless feel that we must nonconcur at this point in time because of a scarcity of information regarding what the proposal would entail. We would like the NIH to provide, through OASH, more information including -

- What type of center is envisioned--an administrative center or a joint administrative/research center?
- Is the ultimate goal of the center concept to coordinate all human genetics research, both intramural and extramural?
- How will the creation of a human genome center impact human genetics programs currently managed by the categorical institutes?
- How would the removal of human genome research funds from NIGMS affect the other genetics research programs administered by the institute, i.e. over $300 million worth of extramural grants in genome-related research? How would these separate but related programs be coordinated?

Mary T. Goeddé
Assistant Secretary
for Legislation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building :
Room :
(301) 496-

JAN 0 4 1989

TO: The Secretary
Through: US _____
COS _____
ES
ASH

FROM: Director, NIH

SUBJECT: Concurrence with Concept of Establishing a Center for Human Genome Research at the NIH -- ACTION

ISSUE

To seek your concurrence with the concept of establishing a center for Human Genome Research at the NIH. As you and I discussed at the PHS Commissioned Corps Centennial Convocation today, I believe the time is appropriate to capitalize on the momentum of the human genome project within the Department and seek your further support.

BACKGROUND

The NIH is supplying much of the impetus for initiating a targeted effort in support of the objectives of the human genome project. The major Federal investment in genomic analysis is being made through the NIH, and the funding for the human genome project at NIH is expected to increase from the current (FY 1989) level of $27.6 million to $100 million in FY 1990. Other Federal agencies have a history of supporting programs that are relevant to the genome project and, in addition, private organizations in this country, as well as private and public agencies in other countries, are becoming active in research on the human genome. Thus NIH's responsibility for leadership and coordination is growing at a surprisingly rapid rate.

Presently human genome research grant applications submitted to the NIH are administered by the National Institute of General Medical Sciences. They are reviewed by (a) special study sections, and (b) the National Advisory General Medical Sciences Council. However, the philosophy of the genome project differs from usual genetic biomedical research in that it represents the development of a resource and will involve

progressively more (a) methods development, targeted research, information systems, (b) rote technology of sequencing, (c) instrumentation development, e.g., sequencer; and (d) central planning, coordination and direction, including international efforts. All of these highly specialized approaches are somewhat at variance with NIH's traditional emphasis on investigator initiated research. These circumstances lead me to believe that it is timely to make plans for converting the NIH Office of Human Genome Research, from what essentially is a staff office, to an independent operating unit, with its own authority to review and award grants with advice from its own National Advisory Council. Thus the human genome project would be managed independently of any other NIH Institute.

DISCUSSION

In FY 1988 when you took the leadership in establishing the Office of Human Genome Research within the Office of the Director, NIH, it was contemplated that the Office would evolve into an independent Center at some time in the future, depending upon the growth of the budget for genome research. Your interest in the genome program, your personal support for it, and the fact that you have made it a Secretarial initiative have had much to do with the gratifyingly rapid rate of its growth. I believe the time has come when serious consideration should be given to the concept that the Office evolve to a Center, perhaps as soon as the beginning of FY 1990. This conversion would have the effect of capitalizing upon the momentum generated by your actions and sustained with the appointment of Nobel Laureate James Watson as NIH Associate Director for Human Genome Research.

The human genome project undoubtedly will be discussed at the upcoming appropriations hearings, probably in the context of the appropriate location for funding the project within NIH. It would be very helpful to have your support in principle of the concept of converting the Office of Human Genome Research to a Center within NIH. Such support from you in discussion with the incoming Secretary would set the tone of the human genome effort at NIH for the critical years ahead.

RECOMMENDATION

I recommend that you indicate your concurrence with the concept that the NIH Office of Human Genome Research be converted to an independent Center for Human Genome Research.

James B. Wyngaarden

James B. Wyngaarden, M.D.

DECISION

Concur_____ Nonconcur_____ Date _____

Otis R. Bowen, M.D.
Secretary

This response was called the place
for this administration. According
to Vida, Jeb Halloway now suggested
a proper presidential pardon should
be done.

4140-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

NATIONAL INSTITUTES OF HEALTH

Statement of Organization, Functions and

Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 54 FR 5682, February 6, 1989), is amended to reflect the following changes within the National Institutes of Health effective October 1, 1989: (1) Abolish the Office of Human Genome Research (HNAB) within the Office of the Director, NIH; and (2) establish the National Center for Human Genome Research (HN3). These changes will more properly reflect the high priority placed on mapping and sequencing complex genomes and the expansion of the genome research effort.

Section HN-B, Organization and Functions, is amended as follows effective October 1, 1989:

(1) Under the heading Office of the Director (HNA), delete the title and statement for the Office of Human Genome Research (HNAB) in their entirety.

(2) After the statement for the Clinical Center (HNJ), insert the following:

National Center for Human Genome Research (HN3). (1) Advises the Director, NIH, and senior staff on all aspects of genomic analysis; (2) coordinates the integration, review, and planning of genomic analysis research; (3) formulates research goals and long-range plans with the guidance of the NIH Program Advisory Committee on Complex Genomes; (4) serves as a focal point on genomic analysis research within NIH, other components of the Public Health Service, and other Federal agencies (e.g., DOE and NSF); (5) fosters, conducts, supports, and administers research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes through: (a) research grants, contracts, and cooperative agreements to institutions and individuals; (b) individual and institutional research training awards; (c) promotion of closer interaction with other bases of genomic analysis research; and (d) collection and dissemination of research findings in these areas; (6) develops plans for the centralized, systematic, targeted effort to create detailed maps of the genomes of organisms; (7) establishes research goals and criteria for review or progress in meeting those goals; (8) sponsors scientific meetings and symposia to promote progress

through information sharing; and (9) fosters national and international information exchange with industry and academia concerning research on complex genomes.

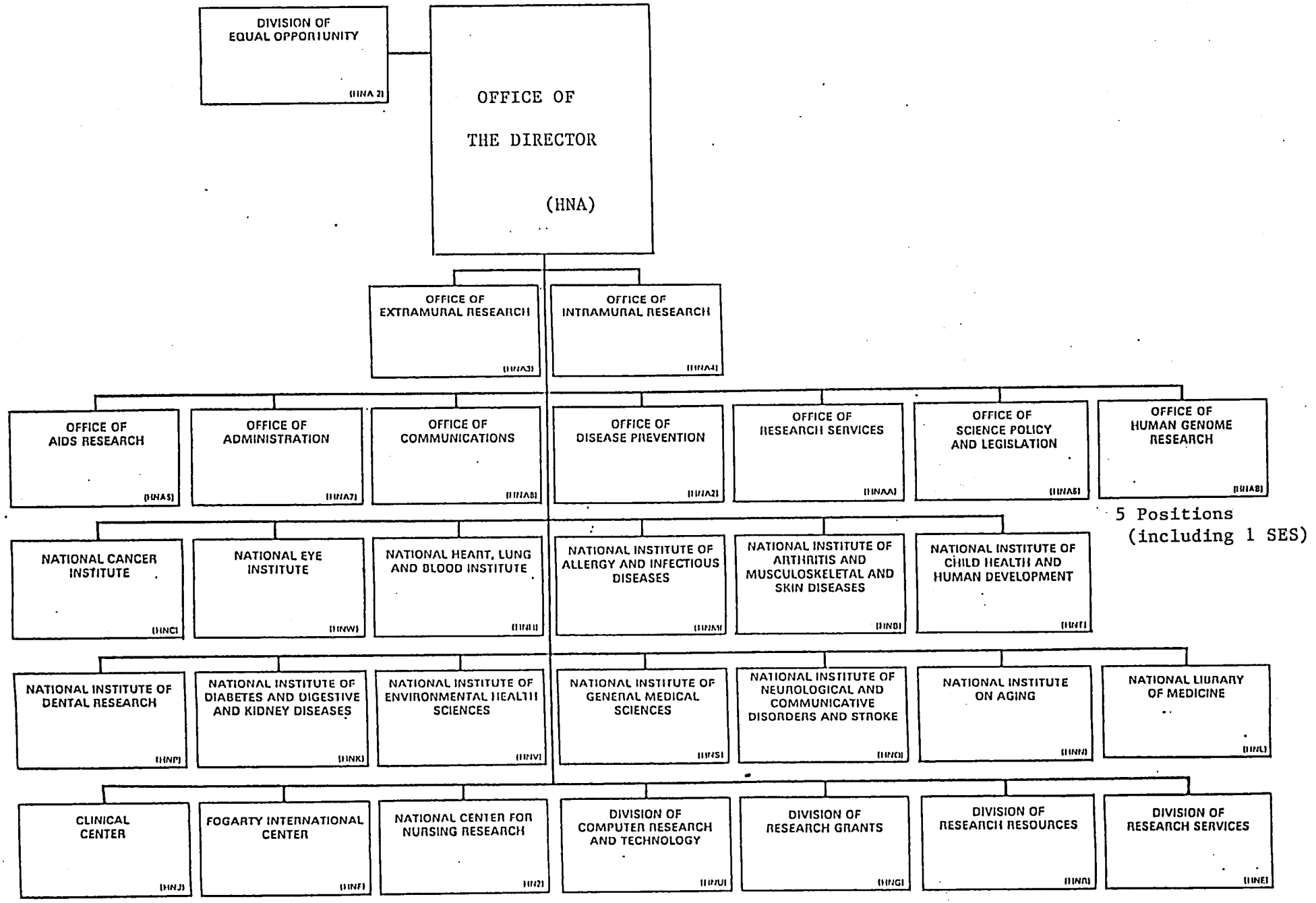
Date

Don M. Newman
Acting Secretary of Health
and Human Services

PRESENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
National Institutes of Health

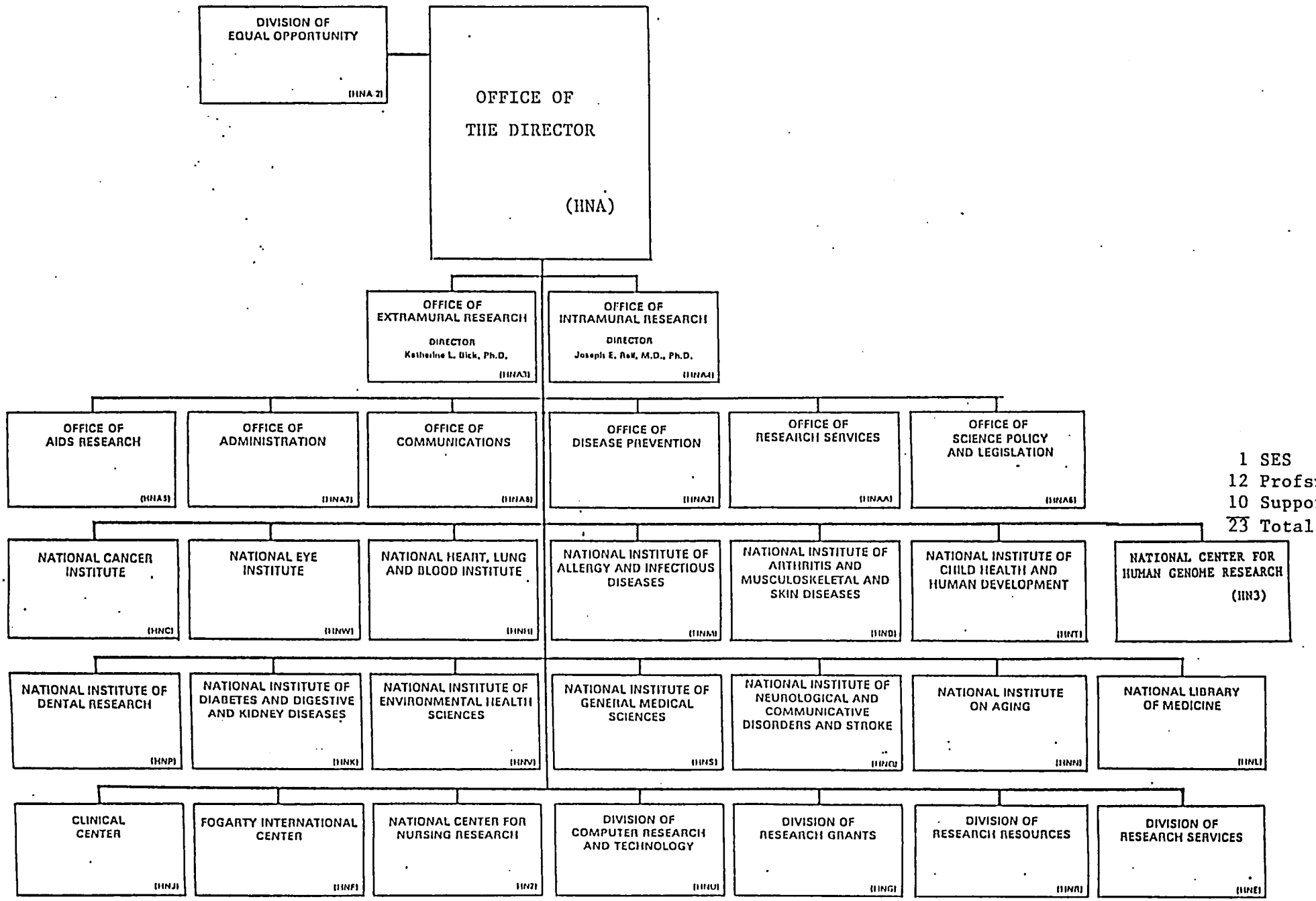


5 Positions
(including 1 SES)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROPOSED

Public Health Service
National Institutes of Health



1 SES
12 Profsnl.
10 Support
23 Total

internal policy file

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date October 3, 1989

From Deputy Director, National Center for Human Genome Research

Subject New Policies

To All Staff of National Center for Human Genome Research

Congratulations! As of this week we are an independent organization. This means we have a number of new responsibilities, and we need to establish policies so that things happen in an orderly fashion.

Policy Number 1:
This policy applies to branch/office/section chiefs listed on the recent organizational staffing list prepared by Jim Vennetti. It is important that I have advanced notice when branch/office/section chiefs will be out of the office. Frequently emergencies occur in the office, and staff are needed to deal with them. Last week I unexpectedly found myself to be the only scientific staff person in the office. We have started a regular weekly calendar to keep track of staff commitments. Please inform Carolyn by Wednesday, if you plan to be out of the office for a half day or more during the following week. This is especially important while we are split between the two buildings. If too many people will be out, we may have to rearrange travel schedules to insure coverage in the office.

Policy Number 2:
We are establishing various internal controls to ensure that appropriate approvals are obtained before funds are obligated. To avoid unilateral decisions on expenditures, at least two individuals will be required to sign off on any document that obligates funds. Until the written instructions are prepared, please check with Jim Vennetti or myself before obligating or making a commitment of funds. This applies to grants, office expenses, travel, training, etc.

Policy Number 3:
When mail is received, whoever opens it should date stamp it and initial it at the top right hand corner. That individual is to ensure that the mail gets to the appropriate person and that copies go to all those who should receive them. Mail should be responded to within

10 working days of receipt, even if the response is not final. I also urge you to keep logs of mail, so that a paper trail is established as to what happens to it. In fact, logs are a good idea for other activities as well.

These policies will be discussed further at our next staff meeting. Meanwhile use this memo as your guide. Branch/Office/Section Chiefs should make sure that their staffs adhere to these guidelines.

We are recruiting as fast as possible to have the people on board that are needed to run NCHGR. Until we are staffed up, things will be hectic. Bear with us, it will get better!!

Jan Vennette for
Elke Jordan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date January 13, 1989

From Director, NIGMS

Subject Issues Related to Proposed Establishment of National Center for Human Genome Research (NCHGR)

To Director, Office of Human Genome Research

This memo is a follow-up to our recent conversation on this subject. I would also expect that it could serve as a basis for discussions at our meeting on January 19.

As you are aware, Dr. Wyngaarden recently made a decision to move ahead with plans to upgrade the Office of Human Genome Research from "essentially a staff office to (the status of) an independent operating unit, with its own authority to review and award grants with advice from its own National Advisory Council." The new Center is to "be managed independently of any other NIH institute" (Reference Dr. Wyngaarden's memorandum to the Secretary, dated January 4, 1989).

In anticipation of this action, I think it would be prudent for us to develop a plan for the orderly takeover by your office of the various tasks associated with administration of the Human Genome Project that have, up until now, been the responsibility of NIGMS staff.

With this in mind, I would suggest the following:

Timing:

At last week's meeting of the NIH Program Advisory Committee on the Human Genome, Dr. Watson and several committee members stressed the importance, from their perspective, of moving quickly to establish the independence of the proposed new Center from NIGMS. And, as you will recall, it was the consensus of the committee that the transition to independent status should take no more than 18 months.

I personally agree with the committee and, assuming Departmental and Congressional approval of the Center's establishment, feel that the best transition point would be the start of fiscal year 1990, which begins October 1, 1989. This would allow NIGMS time to complete action on the obligation of the $27.6 million appropriated to the Institute for Human Genome Project activities in FY 1989, while allowing your office time to develop appropriate plans for the expenditure of the Project's greatly expanded budget for FY 1990.

FY 1990 Congressional Budget Process:

As you are aware, mutually agreed upon narrative and tabular Congressional budget justification materials have already been prepared and sent forward, in support of the Human Genome Project's proposed $100 million budget for FY 1990. Because the concept of an independent Center has not, as yet, been formally approved, these funds have been included in the NIGMS budget request for FY 1990 as a separate line item. That being the case, it is my assumption that I will be responsible for responding to budget questions regarding the Human Genome Project posed at the House and Senate appropriations hearings this spring. Given Dr. Watson's scheduled attendance at these same hearings, however, I also assume that he will be asked to respond to a variety of questions. With this in mind, it is critical that we share all briefing materials (i.e., those prepared by NIGMS, your office, DFM, Dr. Watson, and Dr. Wyngaarden), and any proposed answers to likely questions. Similarly, it is important that we coordinate the responses to all questions that are to be "answered for the record."

Center Staffing:

If the Center is to achieve independence within the timeframe mentioned, I believe it is vital that you begin to recruit additional numbers of both professional and support staff immediately, as well as to arrange for space to house them and for the procurement of furniture, computers, and other necessary equipment. Bill Fitzsimmons of my staff is available to assist you in this regard, if you so desire. It is my assumption, however, that as soon as possible after October 1, 1989, NIGMS staff will transfer all program management, grants management, budget, and administrative management responsibilities to your office. In the interim period, you might wish to have any new staff members that you recruit work with, and receive orientation from, NIGMS staff.

Funding of FY 1989 Awards:

As I made clear during the recent Program Advisory Committee meeting, it is my view that NIGMS's role vis-a-vis the Human Genome Project funds appropriated to the Institute in FY 1989 is that of "trustee" on behalf of your office. For this reason, I will make sure that you receive advance copies of all proposed paylists involving the planned obligation of Human Genome funds this year. I will count on you to inform me of any changes that you or Dr. Watson might wish to propose, either on the basis of program relevance or any other factor that might concern the Advisory Committee.

Research Training:

I am sure you know that research training, and particularly predoctoral research training, remains a high priority within the NIGMS. But, both ongoing budgetary restrictions and the recent decision to increase trainee stipend levels have made it impossible for us to support the number of trainees that we feel are appropriate. Unfortunately, this includes the new

biotechnology-related "Chiles Awards" program being established in FY 1989. Indeed, the President's budget for FY 1990 provides no increase in the number of trainees to be supported under this targeted activity. Because expansion of the biotechnology training program would directly benefit the Human Genome Project and, indeed, is closely related to training designed to accomplish "genome projects," I think we should discuss the possibility of utilizing future year "Genome funds" to achieve such an expansion. As I recall, the need to provide a "not insignificant amount of support" for research training activities was identified as a high priority by the members of the Genome Program Advisory Committee.

Dr. Luther Williams has informed me of the invitation extended to him to serve as an advisor to the Genome Committee's Subcommittee on Training, and I think this is a wonderful idea. I would hope, however, that given both his position as Deputy Director of NIGMS and his status in the scientific community, he would be accorded full membership on this subcommittee rather than be simply an advisor.

Coordination:

While I am aware that the Genome Center is to be an independent NIH component, with BID level status, I know we share the belief that close coordination between the Center and NIGMS is an absolute necessity--both to avoid potential duplications of effort and to achieve the best possible use of available funds. With this in mind, I strongly suggest the establishment of an ex-officio membership position for the Director, NIGMS or his/her designee on the Genome Program Advisory Committee. This would provide NIGMS an interactive advisory role similar to that already accorded the other "major players" in genome-related research (DOE, NSF, HHMI, and the USDA) and would, in my opinion, help to assure maximum coordination.

GenBank and Other Contract Funded Resources:

As noted at the Genome Advisory Committee meeting, the NLM, DRR, and NIGMS all currently support research resource activities which, in one way or the other, impact on the Human Genome Project, but are not funded out of Genome funds. Two of these, GenBank ($4.5 million in FY 1988) and the Human Mutant Cell Repository ($1 million in FY 1988) are administered by, and are primarily supported by, the NIGMS.

Because you have expressed an interest in acquiring control of the GenBank contract, I have given serious consideration to the issue of an appropriate date for the tranfer of the responsibility for this activity to your office. As you are aware, however, the current GenBank contract was only awarded about a year and a half ago, and the contract project officers, Drs. Cassatt and Peterson, have been working feverishly since that time to address a number of serious concerns regarding this contract effort. Because of the critical importance of the GenBank contract, as well as the huge investment of time and effort already made by Drs. Cassatt and Peterson on this project, I am very reluctant to "change horses in midstream" and transfer the contract to you in

FY 1990, as you have suggested. I would, instead, prefer that NIGMS administer the contract through to its completion in 1992, with your office assuming full responsibility for GenBank at that point. This would take maximum advantage of our project officers' in-depth knowledge of GenBank's personnel and operations in the short run, while allowing your office to immediately take full responsibility for program planning efforts designed to tailor the recompetition of the contract to the expanding needs of the scientific community as the Genome Project expands. We would, of course, immediately involve you and your staff in all decision-making and review activities affecting GenBank.

A related issue is the future of Bionet and the Protein Identification Resource (PIR), both of which, up until now, have been funded and administered by DRR. As noted at the Genome Advisory Committee meeting, the study section which reviewed the most recent PIR renewal application effectively truncated its next funding period to assure that the recompetition of this project will coincide with that of the GenBank contract--a move designed to assure better coordination of their interrelated functions. Dr. Cassatt has been working with Drs. Holloway and Hirsch of DRR in an effort to carry out the wishes of the study section--with which we agree--and I believe that it would be to everyone's advantage if a member of your staff were assigned to work with him, with an eye toward eventually taking over his duties in this regard.

Dr. Cassatt has also been working with Dr. Holloway with regard to Bionet, and currently is of the opinion that major portions of the Bionet contract might be "folded into" the GenBank workscope. Obviously, this also requires further discussion.

Given Dr. Greenberg's report to the effect that only about 12 percent of the Human Mutant Cell Repository's activities relate to the Genome Project, it is my assumption that this contract will remain in NIGMS, but that your office and the Genome Advisory Committee would be given periodic updates on the Cell Bank's activities. If this is not consonant with your view, we can discuss this contract further.

You should also be aware that, because of the increased workload associated with both the Cell Bank and GenBank contracts, NIGMS provided a personnel slot to DCG during the past year, to allow the hiring of a full time GS-13 contract specialist (Mr. Wayne Thomas), able to dedicate his time to these projects. If your office takes on responsibility for GenBank and/or other contracts in the future, we will need to work something out regarding Mr. Thomas' time.

Program Announcements and RFAs:

Since responses to any program announcements or RFAs issued in the near or distant future will not result in the expenditure of Genome Funds until FY 1990, I think that your office should be responsible for their preparation and publication. As with the program announcement on "ethics," we would be pleased to cooperate in this regard.

I may, of course, have left a few issues off this list, but we can add to it at our January 19th meeting.

Ruth L. Kirschstein

Ruth L. Kirschstein, M.D.

NOTE TO DR. JORDAN

Subject: Update on Administrative Position

Elke:

I met with Marilyn Kunzweiler this afternoon regarding her possible reassignment to your office as the administrative officer. We discussed the following:

I had discussed several days ago with Fred Walker our options for classifying a position of this type in your office and he advised that, if the Genome office remains in the Office of the Director at the Associate Director level, it would be very difficult for Personnel to classify the position any higher than the GS-12 level. If the office becomes a Center, there is no problem classifying the job at the GS 13/14 level (Executive Officer position similar to the one in NCNR). In order for Marilyn to take the job, we would have to laterally transfer her to Genome and when it becomes a Center, advertise the job and select her. Marilyn is presently a GS-12 eligible for promotion and there is a strong possibility that a GS-13 may be approved where she is. So, there is a risk associated with her taking the job.

She asked if she could have the weekend to think over the situation. She will call on Monday. If she is interested, I told her we would like to call several references. She offered the names of several individuals who are familiar with her work: Steve Ficca (x2411), Bill Harlan (x2533), and Larry Friedman (x1706), all of NHLBI. Bill Friedewald knows Marilyn and thinks very highly of her I believe. You might want to give him a call, also, as an impartial source of information. I assume you will want to do the reference checking yourself, but if you are busy with other matters I will be happy to assist.

I will keep you posted on this and the space front as things unfold.

Colleen 2/10/89

Colleen

cc: Jack Mahoney

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : Shannon
Room : 102
(301) 496- 4466

DRAFT

NOTE TO DR WYNGAARDEN

Subject: Establishment of a National Center for Human Genome Research

Jim:

Since receiving the responses from the various staff offices within the Office of the Secretary to your memorandum of _____ regarding the establishment of the Center, we have taken several steps to plan for its establishment:

1. Dr. Jordan developed a proposed staffing plan outlining the number of people that will be required assuming that the Center will be fully operational in FY 1990. Her proposal which assumes that personnel - any others? public affairs EEO legislation administrative services will be provided by another BID is shown as Attachment A.

2. Dr. Jordan and I met with Dr. Kirschstein to get a better understanding of any flexibility in her desire to have the genome effort transferred to the new Center on October 1, 1989. There seemed to be a small element of flexibility in that she seemed agreeable to a January 1, 1990 transfer date, although she firmly wants to have the Center established as quickly as possible.

where is it?

3. Fred Walker and Colleen Barros of my staff have constructed a time line for the hiring of 18 add'l ~~25~~ people and identifying space for this Center.

It will take at least 5 months to hire these people after all of the position descriptions are written. (It probably would be wise to overallocate a position to the personnel office at least temporarily to accommodate this additional workload and avoid further diminution of services to the rest of OD.)

4. A senior administrative officer needs to be hired to handle the myriad actions that have to be organized and completed including the development of the position descriptions noted above. Colleen Barros has identified such a person and we should know by Friday if the person will accept the job. need to look at some others also.

5. I have met with Dr. Watson to discuss the types of personnel appointments that will allow him to direct the Center. He was agreeable to becoming a Special Expert, although it will not allow us to pay his travel costs and will substantially reduce the amount that we are now paying him as a Regular Expert. I will be pursuing the acceptability of this appointment with Bill Forbush and Tom McFee. I also told Dr. Watson that Bob Lanman should once again review for conflict of interest since he would now have operational responsibilities.

IMMEDIATE NEXT STEPS

Basically, the following decisions need to be made on the assumption that we want to have a fully operational Center as early in FY 1990 as possible:

1. Level of Resources:

The level of resources (23 FTEs) proposed by Dr. Jordan seems appropriate if the Center is to assume full responsibility for managing a program of $100 million in FY 1990. This obviously is a higher level of resources than currently budgeted. The FY 1990 President's Budget had assumed a multi-year transition and requested a total of 12 FTEs and $. The FTE allocations to other BIDs would have to be reduced to accommodate this additional requirement and support costs would need to be reallocated from within the genome budget. Accommodations will also have to be made in 1989 as most of unbudgeted hiring will occur this year.

- specifically, should not assume that these genome specific FTE's in NIGMS should be reallocated

A decision on the level of resources is needed to complete the proposed organizational package. In addition we need to clarify the relationship between the Center and other BIDs who have genome-related projects. This was a concern expressed in the responses from OS staff offices to our previous correspondence.

- NIGMS
- NLM

✓ reiterated ?

2. Hiring of Staff, etc.

The preliminary estimates from my staff regarding hiring and space lead-times indicate that if we started a concerted effort and everything went smoothly, we might be fully operational by.... However, since nothing ever goes smoothly, it is reasonable to assume that it will take at least another 3 months at a minimum. This assumes that we begin this undertaking now before there is Secretarial approval of the

organizational package. Obviously, this strategy is appropriate only if we are absolutely confident of Secretarial approval; otherwise we will have hired staff that would have to be placed elsewhere.

If we adopt a more cautious approach and begin a concerted effort after Secretarial approval, it will likely add another 2-3 months to the projected completion date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date February 9, 1989

From Director, Office of Human Genome Research

Subject Establishment of a National Center for Human Genome Research

To Associate Director for Administration

Some immediate responses to your draft note to Dr. Wyngaarden about the establishment of a National Center for Human Genome Research.

a. Item 1. My staffing plan assumes that, in addition to personnel, certain other administrative services, such as public affairs, EEO, and legislative affairs, will be provided by another BID or by the OD.

b. Item 3. The number of additional people that would have to be hired by October 1, 1989 is 18. I have not seen any plan or time line for the identification of space for the Center.

c. Item 4. If the implication of the last sentence is that we may have an accepted job offer by Friday, that is premature. Although we were favorably impressed by the first person we spoke with about the administrative officer job, we are not prepared to make a decision by Friday, as we have not obtained any references on that individual nor have we yet met any other candidates.

d. Level of resources. With respect to finding the necessary FTE's by reducing the allocations to other BID's, you should keep in mind that there are currently no FTE's in NIGMS that are dedicated to the genome project. That Institute has been handling the genome work on top of its exisiting responsibilities, without any additional FTE's. Therefore, there are no slots that could be transferred from NIGMS to the new Center with the justification that the FTE's go along with the work being transferred.

e. Relationship between the Center and other BID's. In the general case, this is a question of the limits of the Human Genome Program. The establishment of the Center should not have the effect of intruding upon the existing interest of other BID's. Rather, by supporting the development of general genome-related information and materials, the Center's activities should have the effect of supporting and encouraging the genetics activities of the categorical institutes.

With regard to NIGMS, the situation is more complex. To a first approximation, since the genome set-aside is a line item in the NIGMS budget, transfer of those funds should not affect other NIGMS programs. Scientifically, however, there will continue to be a very close relationship between the research interests of the Center and the research interests of NIGMS, particularly the Genetics program. Questions of overlap and appropriate areas of responsibility will exist and will evolve as the science develops. A very close working relationship between the staffs of the Center and NIGMS will need to be maintained so that such questions can be discussed, negotiated, and resolved. On the other hand, it should also be kept in mind that the close relationship in areas of interest between the Center and NIGMS represents an opportunity for synergism and mutual progress.

Another BID with which the Center will have closely related interests is NLM. Here too, constant interaction will be necessary in order to avoid unnecessary redundancy, to ensure that the needs of both programs are met, and to take advantage of opportunities to foster scientific advances of mutual interest.

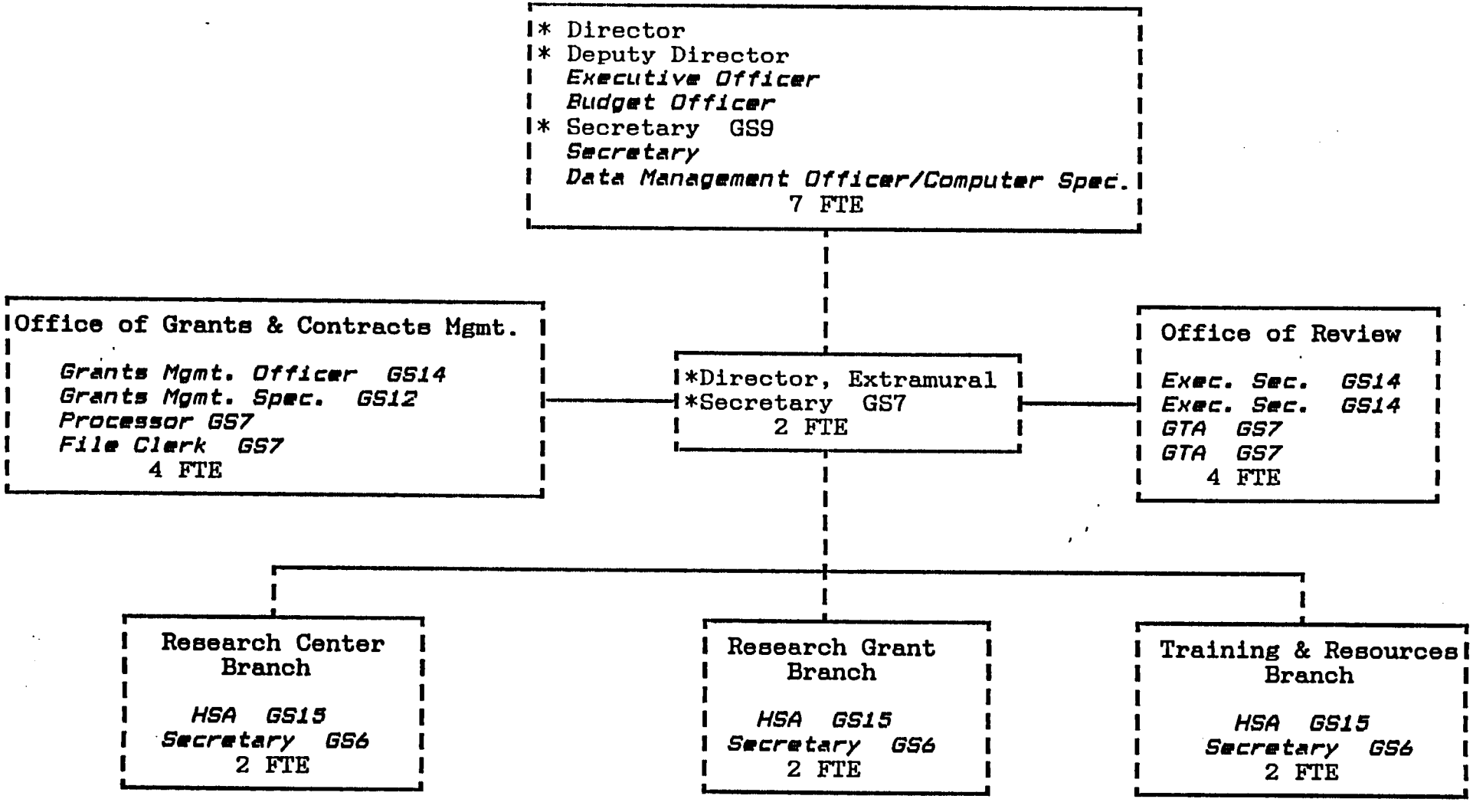
Finally, the subject of the relationship between the Center and other BID's allows us to raise the question of how genome-related projects in the intramural program should be encouraged and supported. Dr. Watson is interested in stimulating the development of an intramural program, through provision of incremental support. Some preliminary discussions in this regard have already been held.

Elke Jordan

Elke Jordan, Ph.D.

OFFICE OF HUMAN GENOME RESEARCH

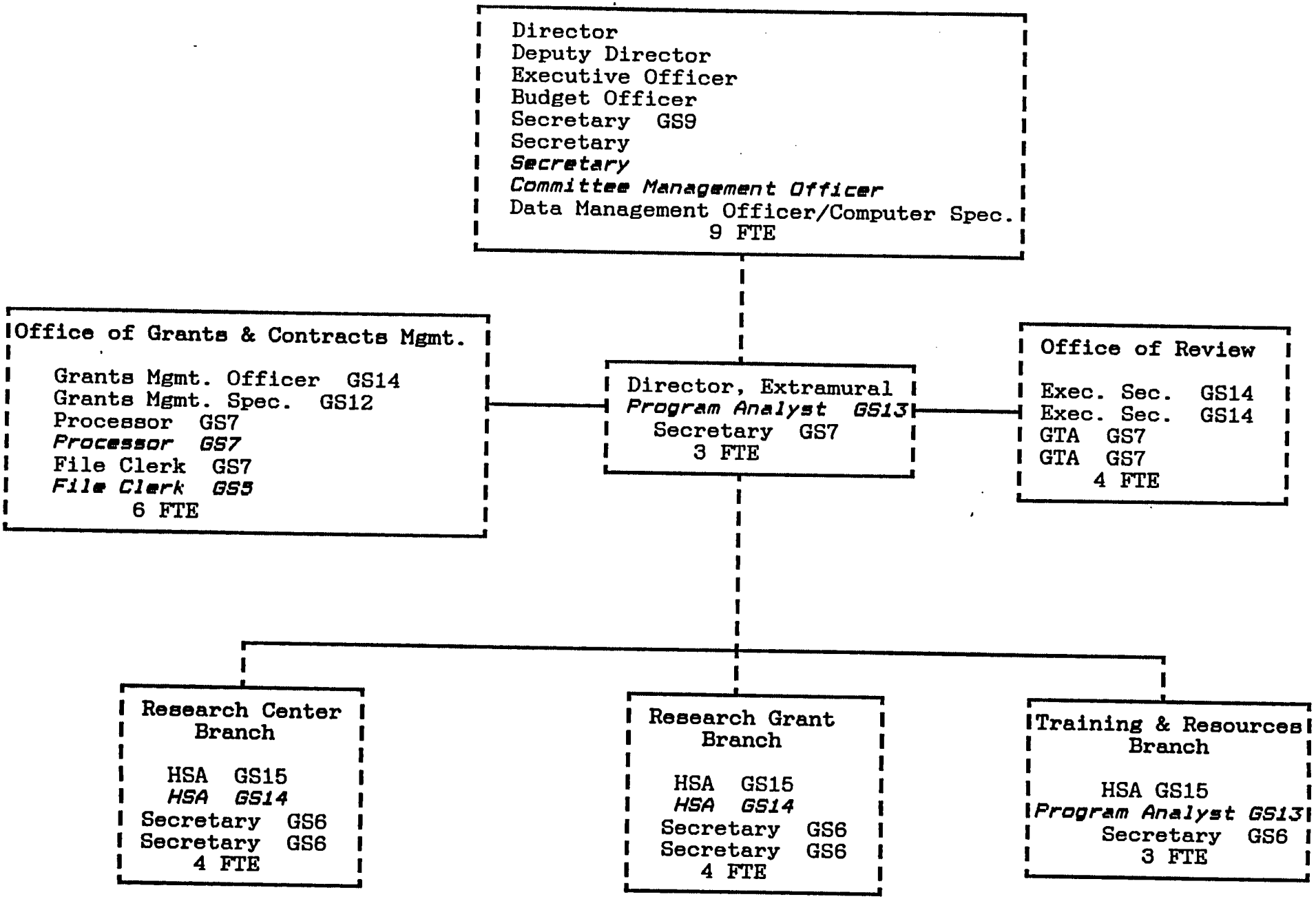
STAFFING NEEDED BY OCTOBER 1, 1989**



** Assume type 5's remain in GM, otherwise 3-4 extra FTE
* On board FY89

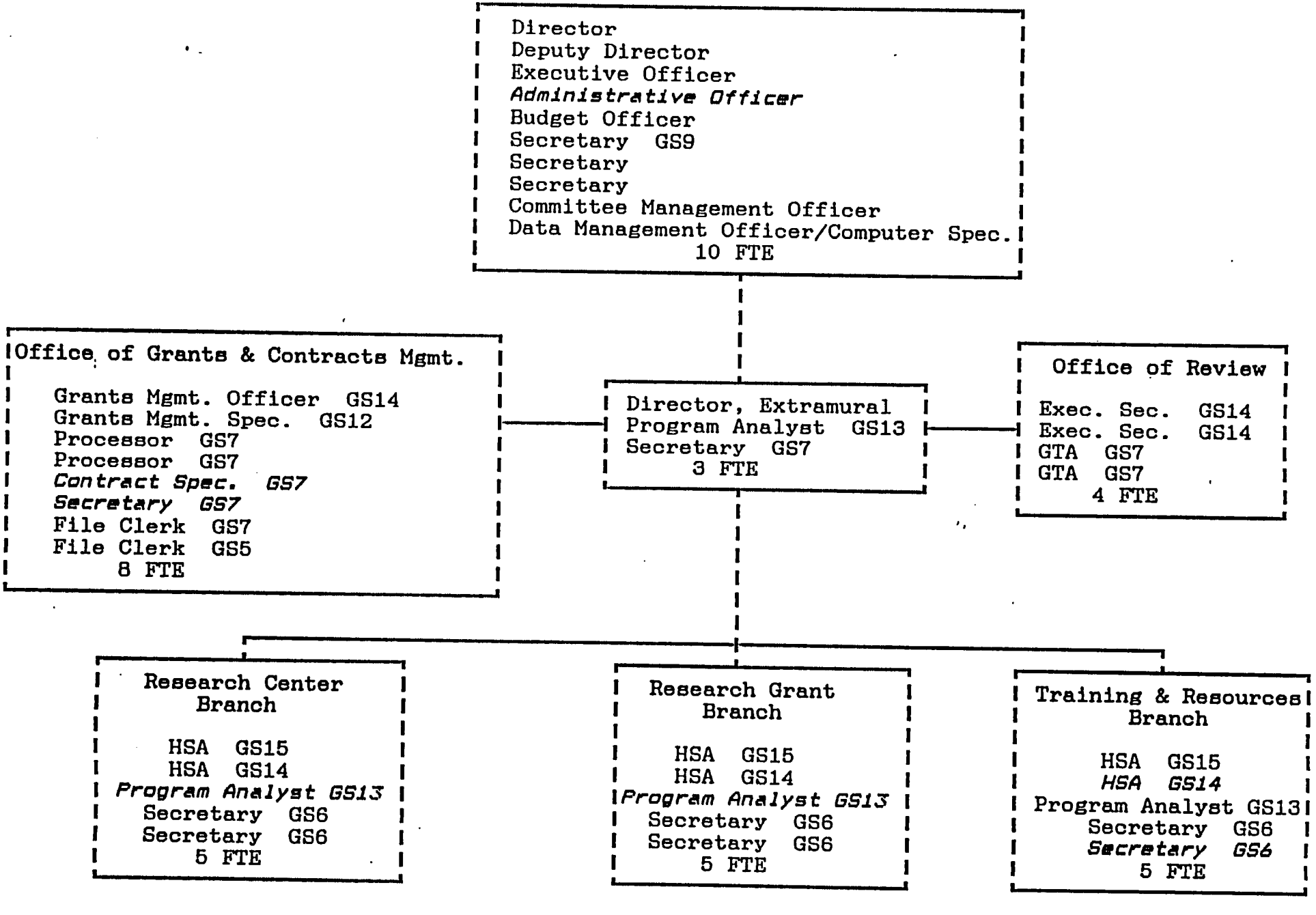
OFFICE OF HUMAN GENOME RESEARCH

STAFFING NEEDED BY END OF FY 1990



OFFICE OF HUMAN GENOME RESEARCH

FULL STAFFING



comptGtt offices
Exec Admin office 8
Personnel 3
budget 8
data mgt 7-8
Gr Mgt 23
2
5
30

Review 12

STAFFING OF GENOME CENTER
WHEN FULLY INDEPENDENT OF NIGMS

- * Director
- * Deputy Director
- * Executive Officer — Administrative officer
- * Budget Officer
- * * * 3 Secretaries
- * Committee Management Officer
- * Data Management Officer/computer spec

9 FTE

GM10 14*
spec 12*
process 7,7*
contr's 13
6
ext 7,5*
files

payback
council prep

Office of Grants & Contracts Management
Council, files
8 FTE

* Director, Extramural
* 1 Program Analyst
* 1 Secretary
3 FTE

Office of Review
2 Exec. Sec .
2 GTA's
4 FTE

GS14*
GS14*
GS7*
GS7*

* GS15
* GS14
GS13
* GS6
* 6

Research Centers Branch
2 HSA
1 Prog.Analyst
2 Secretaries
5 FTE

* GS15
* 14
13
* 6
* 6

Research Grants Branch
2 HSA
1 Prog.Analyst
2 Secretaries
5 FTE

* GS 15
14
* 13
* 6
6

Training & Resources Branch
2 HSA
1 Prog.Analyst
2 Secretaries
5 FTE

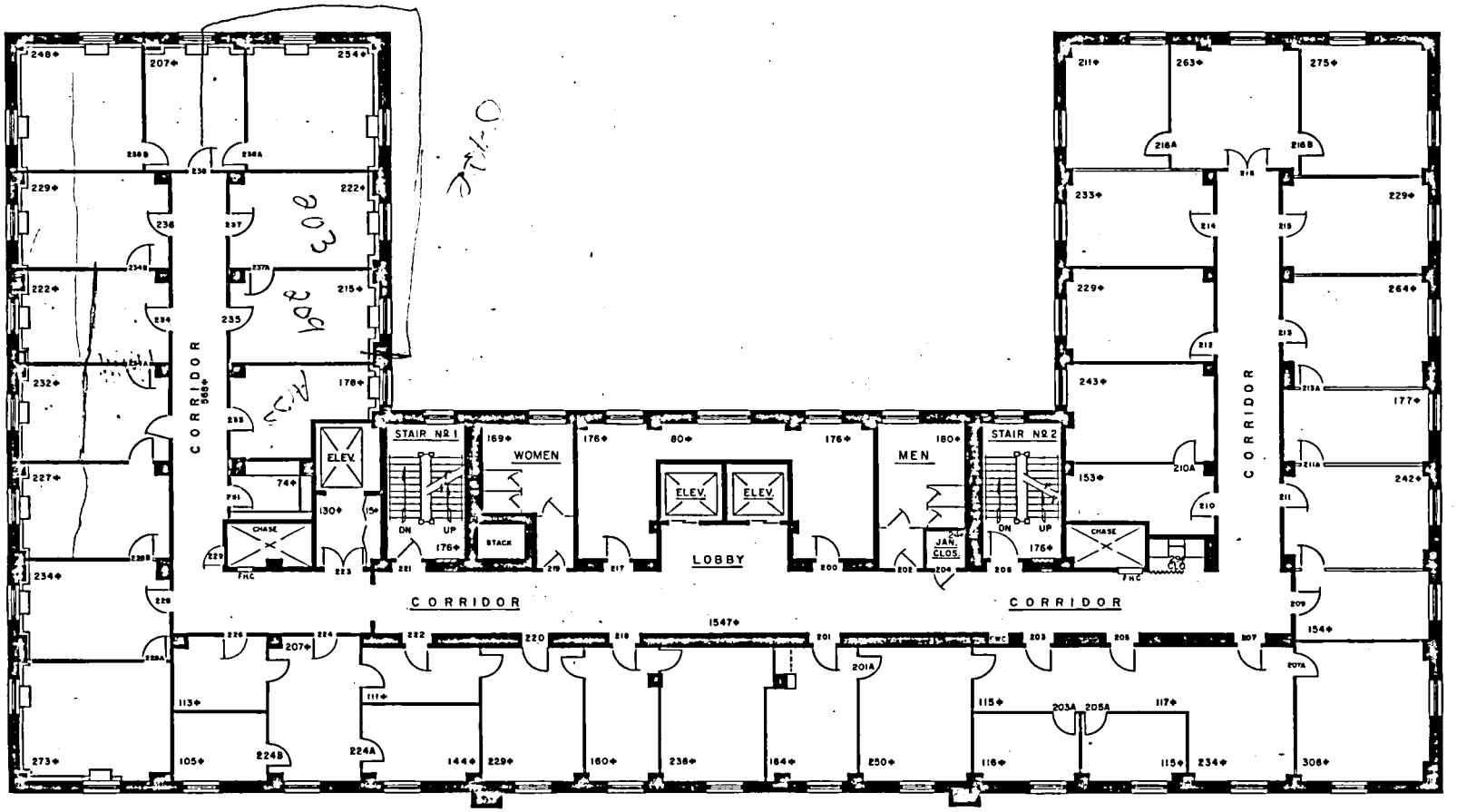
F, T, Kawada

contracts
databases
conferences

* on board FY89 - 5 FTE
* needed by Oct 1, 1989 + 18 FTE (assume type 5 remain in GM) 3-4 extra if not
* needed by end of FY90 ~~+0~~ FTE

rest by end of FY91 + 6 FTE

39 Total



NATIONAL INSTITUTES OF HEALTH BETHESDA, MARYLAND		
SPACE MANAGEMENT BRANCH		
BUILDING 1 SECOND FLOOR PLAN		
DATE: 6-6-61	SCALE: 1/8" = 1'-0"	SHEET: 1 OF 1
DRAWN: KE.	DWG. NO. 1-2-200	

December 28, 1988

Director, Office of Human Genome Research

Space and FTEs for OHGR

Deputy Director, NIH
and
Associate Director for Administration

FTEs

During recent conversations with Drs. Watson and Wyngaarden, it has become clear that OHGR needs more staff, as soon as possible, in order to keep up with demands of the program. For the remainder of FY 1989, we can get by with two additional FTEs. We will attempt to make up the rest of our deficit by finding individuals to help us who do not require FTEs. I would be happy to discuss this need with you

Space

Our current space on the third floor is completely inadequate for our current staff. We expected to be out of that space by now and are very anxious to move in the shortest possible time. The situation here is seriously impeding progress, now that we have all our positions filled. Could we have some indication when we are moving?

The space needs for the additional two FTEs could be met if we could have one more office on the second floor, i.e., room 233, adjacent to our space. Since the AIDS office is already split, perhaps the individual currently slated for room 233 could be accommodated in Building 31.

If we indeed get seven additional FTEs in FY 1990 as currently projected, we will of course need much more space. Clearly, so much space is not available in Building 1, and we will need to be split. It will be very important to have the splinter group close by. Building 31 and 38A were mentioned: that would be manageable. Further away would be unworkable for such a small Office (or Center) of staff that will all be working closely together.

Some of the OHGR staff or slots may need to be assigned to NIGMS, so long as NIGMS is still performing a substantial part of the human genome work, a situation that will pertain for 3 to 5 years, regardless of whether OHGR becomes a Center. NIGMS cannot absorb all this activity with current staff. Since NIGMS has no space for additional people, space needs in NIGMS must also be considered.

Elke Jordan, Ph.D.

cc:
Ms. Colleen Barros

JAN 04 1989

TO: The Secretary
Through: US _____
COS _____
ES _____
ASH /s/ 1/5/89

FROM: Director, NIH

SUBJECT: Concurrence with Concept of Establishing a Center for Human Genome Research at the NIH -- ACTION

ISSUE

To seek your concurrence with the concept of establishing a center for Human Genome Research at the NIH. As you and I discussed at the PHS Commissioned Corps Centennial Convocation today, I believe the time is appropriate to capitalize on the momentum of the human genome project within the Department and seek your further support.

BACKGROUND

The NIH is supplying much of the impetus for initiating a targeted effort in support of the objectives of the human genome project. The major Federal investment in genomic analysis is being made through the NIH, and the funding for the human genome project at NIH is expected to increase from the current (FY 1989) level of $27.6 million to $100 million in FY 1990. Other Federal agencies have a history of supporting programs that are relevant to the genome project and, in addition, private organizations in this country, as well as private and public agencies in other countries, are becoming active in research on the human genome. Thus NIH's responsibility for leadership and coordination is growing at a surprisingly rapid rate.

Presently human genome research grant applications submitted to the NIH are administered by the National Institute of General Medical Sciences. They are reviewed by (a) special study sections, and (b) the National Advisory General Medical Sciences Council. However, the philosophy of the genome project differs from usual genetic biomedical research in that it represents the development of a resource and will involve

progressively more (a) methods development, targeted research, information systems, (b) rote technology of sequencing, (c) instrumentation development, e.g., sequencer; and (d) central planning, coordination and direction, including international efforts. All of these highly specialized approaches are somewhat at variance with NIH's traditional emphasis on investigator initiated research. These circumstances lead me to believe that it is timely to make plans for converting the NIH Office of Human Genome Research, from what essentially is a staff office, to an independent operating unit, with its own authority to review and award grants with advice from its own National Advisory Council. Thus the human genome project would be managed independently of any other NIH Institute.

DISCUSSION

In FY 1988 when you took the leadership in establishing the Office of Human Genome Research within the Office of the Director, NIH, it was contemplated that the Office would evolve into an independent Center at some time in the future, depending upon the growth of the budget for genome research. Your interest in the genome program, your personal support for it, and the fact that you have made it a Secretarial initiative have had much to do with the gratifyingly rapid rate of its growth. I believe the time has come when serious consideration should be given to the concept that the Office evolve to a Center, perhaps as soon as the beginning of FY 1990. This conversion would have the effect of capitalizing upon the momentum generated by your actions and sustained with the appointment of Nobel Laureate James Watson as NIH Associate Director for Human Genome Research.

The human genome project undoubtedly will be discussed at the upcoming appropriations hearings, probably in the context of the appropriate location for funding the project within NIH. It would be very helpful to have your support in principle of the concept of converting the Office of Human Genome Research to a Center within NIH. Such support from you in discussion with the incoming Secretary would set the tone of the human genome effort at NIH for the critical years ahead.

RECOMMENDATION

I recommend that you indicate your concurrence with the concept that the NIH Office of Human Genome Research be converted to an independent Center for Human Genome Research.

/S/ James B. Wyngaarden, M.D

James B. Wyngaarden, M.D.

DECISION

Concur_____ Nonconcur_____ Date _____

Otis R. Bowen, M.D.
Secretary

NIH/OD/OHGR:EJordan:cem 12/30/88 496-0844
Rewritten NIH/OD:SWhaley:JWyngaarden:VBeaven:EJordan:cem
1/4/89 496-0844
Official file located in OD office
Contact: Elke Jordan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building :
Room :
(301) 496-

TO: The Secretary
Through: US _____
COS _____
ES _____
ASH _____

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James B. Wyngaarden, M.D.

DECISION

Concur_____ Nonconcur_____ Date _____

Otis R. Bowen, M.D.
Secretary

02-Dec-88

National Institutes of Health
National Center for Human Genome Research
FY 1989 & 1990 Budget Estimates
(Dollars in Thousands)

	FY 1989	FY 1990 Request Level 1/
Personal Services:		
Director	$87	91
Deputy Director, ES	81	85
Health Sci. Adm. GS-15	56	72
Secretary, GS-9	30	34
Secretary, GS-5	19	19
Health Sci. Adm. GS-14		62
Health Sci. Adm. GS-14		62
Program Analyst GS-13		52
Program Analyst or Adm. Officer GS-12		44
Computer Scientist GS-14		62
Secretary GS-6		22
Secretary GS-6		22
Subtotal, P.S.	273	627 2/
Other:		
Travel	5	30
Furniture	0	25
Equipment (PCs etc.)	10	60
Advisory Committee	90	153 3/
Other Admin. Exp.	22	45
Subtotal, Other	127	313
Total	400	940

1/ Assumes that grants management and contract support functions will remain in the BIDs that are currently funding these activities. These functions will be reviewed for possible transfer to the NCHGR in subsequent fiscal years.

2/ Excludes 2 FTEs for Personnel & Budget support functions. (Estimated cost is $100K)

3/ Twelve-member advisory committee for 3 meetings plus support and sub-committee meetings.

Office of the Director
Office of Human Genome Research
FY 1988 - 1990 Budget Estimates
(Dollars in Thousands)

	FY 1988	FY 1989	FY 1990 Comm. Base	FY 1990 Add'l Req	FY 1990 Prof Judge Level
Personal Services:					
Assoc. Director - Spec.Exp. (June 1)	$29	$87	91		91
Deputy Director, ES-4 (June 1)	27	81	83		83
Prof. Engineer, GS-14 (July 1)	14	56	57		57
Secr./Admin. Ass't, GS-9 (July 1)	7	27	28		28
Secretary, GS-7 (July 1)	6	22	22		22
7 Additional FTEs				320	320
Subtotal, P.S.	83	273	280	320	600
Other:					
Travel	15 1/	5	5	25	30
Furniture	23 2/	0	0	25	25
Equipment (PCs etc.)	15 2/	10	10	50	60
Advisory Committee	30	90	93	60	153
Other Admin. Exp.	14	22	23	20	43
Subtotal, Other	97	127	132	180	312
Total	180	400	412	500	912

1/ Includes $14K for household move for the Assoc. Dir. and $1K for domestic travel.

2/ Furniture is budgeted at $3,000 per employee, $7,000 each for the Assoc. Dir. and Deputy Dir. In addition, three PCs (including printers and software) are included in the budget at an estimate of $5,000 each.

D R A F T

NATIONAL CENTER FOR HUMAN GENOME RESEARCH, NIH

Implementation Plan

In recognition of the high priority placed on mapping and sequencing the human genome and the substantial funding for this program anticipated in fiscal year 1990, it is proposed to convert the existing Office of Human Genome Research (OHGR) into the National Center for Human Genome Research (NCHGR).

Function of the NCHGR

The Center will assume responsibility for all funds appropriated for the Human Genome program at the NIH. Research goals and long-range plans will be formulated with the guidance of the NIH Program Advisory Committee on the Human Genome. Given the broad involvement by a number of federal agencies and other funding organizations in research related to the characterization of complex genomes, the Center will be the focus at NIH for coordination spanning these areas:

- Overall coordination within NIH

- Interagency coordination between NIH and other Federal agencies and non-Federal research-funding organizations

- Collaboration with industry and academia

o International cooperation

The National Center for Human Genome Research will develop a broad research program on complex genomes that is a centrally planned, systematic, targeted effort to create detailed maps of the genomes of several organisms. A considerable amount of technology development will be required to accomplish this task. The program will utilize a variety of extramural grant and contract mechanisms; it may also include intramural research. A critical component of the program will be the development of resources to support the human genome initiative and to collect, organize, and distribute the information produced so as to make it maximally useful to the scientific community.

Transition from Office to Center

The assumption of new duties will require a substantial expansion of staff over the current level. Since there is no existing cadre of staff to transfer from other BIDs, an extended transition will be needed during which appropriate staff can be recruited to allow the Center to gradually assume more of the functions involved in managing grants and contracts.

During the first year, the expanded Center staff will assume all planning and coordinating functions for the genome project, some of which are currently carried out by the BIDs. It is expected

that the Advisory Committee will rapidly develop new initiatives, as well as recommend establishment of working groups and other activities requiring intense staff support. The establishment of genome research centers and a research training program will also involve considerable Center staff effort. In addition, during the first year, major emphasis will be placed on the establishment of new resources (e.g. physical mapping databases) and the improvement and expansion of existing resources.

Existing grants and contracts programs will continue to be managed by the BIDs currently managing them through interagency agreements with the NCHGR, and with oversight by Center staff. Most of this activity is currently, and would remain, with NIGMS. This Institute has knowledgeable staff who will assure that the standards applied to genome grants are comparable to those applied to other basic research grants. The National Advisory General Medical Sciences Council has the expertise to review genome grants.

NCHGR staff will gradually assume grant and contract operating functions as positions become available and individuals with appropriate expertise are hired. Initially, the center will concentrate on developing and managing new programs; eventually all activities will be transferred to the Center. The full transition is expected to take three to four years and will require at least 22 positions over the FY 1989 level, depending on the budget level. With this staffing, the Center would assume

all grants and contracts management responsibility, but would still need to share overhead functions such as budget and personnel.

In order to award its own grants, the NCHGR will need an Advisory Council. This should not be the same group as the Program Advisory Committee because the functions and membership requirements are different. Establishment of a Council will need to be considered in year three or four of the transition. The Program Advisory Committee should also be retained to provide for continued, detailed planning of the Human Genome effort.

STAFF PLAN FOR OFFICE OF HUMAN GENOME RESEARCH/ NATIONAL CENTER FOR HUMAN GENOME RESEARCH

FY 89 OHGR
- Associate Director, Spec. Exp.
- Director, OHGR, ES-4
- HSA, GS-15
- Secretary, GS-9
- Secretary, GS-7

FY 90 OHGR or NCHGR
- Additional staff over FY 89 level (+ 7 FTE)*
- 2 HSA, GS-14
- Program Analyst, GS-13
- Program Analyst or Administrative Officer, GS-12
- Computer Scientist, GS-14
- 2 Secretary, GS-6

FY 91 } FY 92 }
- Additional Staff assigned to positions as needed by scientific developments, leading in increments to the level shown for FY 93

FY 93 NCHGR
- Additional staff over FY 89 level (+20 FTE)
  - HSA, GS-14 } review of special initiatives
  - GTA, GS-7 } (RFA, training, centers, contracts)
  - **Computer scientist, GS-14
  - HSA, GS-14
  - **Program Analyst, GS-13
  - 2 Secretaries, GS-6

  } Management of resource contracts

  - HSA, GS-15
  - **2 HSA, GS-14
  - Program Analyst, GS-13
  - **2 Secretaries, GS-6
  - 1 Secretary, GS-7

  } Management of research, training, centers

  - 2 Grants Managt Spec, GS-12
  - 2 Grants Clerks, GS-7
  - Contract Specialist, GS-12

  } Fiscal management of grants and contracts, tracking of expenditures

  - **Program Analyst, or Admin Officer, GS-12

  } to support Advisory Committee & Council

  - 2 clerks, GS-5

  } Official files, Council preparation, typing

*During the transition, some of the new staff may have to be detailed to NIGMS

**Positions added in FY 90 (not necessarily doing same job)

D R A F T

WYNGAARDEN: TALKING POINTS RE CENTER FOR HUMAN GENOME RESEARCH

The prospect of a budget of $100 M for genome research in FY 1990 raises a number of issues, including the possibility of converting the Office of Human Genome Research to a National Center for Human Genome Research.

1. Regardless of center status, OHGR will need more staff to plan and initiate new programs such as center grants, core grants, and training grants, to coordinate ongoing research programs and to carry out Advisory Committee recommendations. The seven new FTEs proposed in the FY 1990 budget would be needed to handle this additional workload.

2. The prospect of conversion of OHGR to a Center itself poses certain problems:

a. If OHGR were to become a Center, it would not be realistic to expect the Center to immediately assume complete responsibility for all grants and contracts funded with genome dollars. To do so would require about 22 FTEs above the FY 1989 level. Recruitment of new personnel would be required to fill these positions because there is no existing cadre of "genome staff" to draw on, either in NIGMS or in other BID's. Currently, most of the genome-associated work is handled as extra duties for existing staff. Recruiting and training the additional staff would take time.

b. If the Genome Center were to fund grants, it would need an Advisory Council. It would not be desirable for the new Program Advisory Committee to act as Council because this could lead to conflict of interest. Councils also have less flexible membership requirements than the Advisory Committee, which was designed to be a purely scientific body.

3. The practical solution to these problems is to plan for a fairly long transition period between an initial Genome Center and a fully independent Genome Center, during which the activities of the Center would be focussed on stimulating new research activities and developing new mechanisms for funding genome research. During this period, most existing programs (particularly the R01 grant program) would continue to be managed by the BIDs that currently manage them, through interagency agreements with the Genome Center. As staff is hired, the Genome Center could gradually assume more direct operating responsibility, especially for the new initiatives (e.g., research center grants) and resources (mostly contract funded).

4. Responsibility for management of research grants would remain with NIGMS. OHGR staff and Dr. Watson believe that continued use of NIGMS to handle grants, including review by NAGMS Council, would be economical and would provide several important benefits:

a. grants would continue to be administered by knowledgeable, trained staff;

b. the community would be assured that review standards would continue to be the same as those for other basic research;

c. close integration of genome research with related basic research would be maintained.

This arrangement could be maintained for the foreseeable future, until such time as the nature of the human genome research program changes so as to make it incompatible with management by NIGMS. The agreement with NIGMS would be reviewed annually to make sure it is working properly.

5. During this transition period, Genome Center staff would obviously work very closely with NIGMS and other BID staff to assure Center objectives are met.

6. The extra workload in NIGMS will likely require that the Genome Center "lend" slots to NIGMS for a period of time. This and other details would need to be negotiated with Ruth Kirschstein. She has reacted positively to the overall proposal in a preliminary discussion.

7. The most important coordination initially will be needed for the resources associated with the genome project. These should be, and in most cases are now, funded by contract and therefore do not require a Council. In FY 1990, the additional funds that appear to be in the offing would allow the human genome budget to pick up several projects currently funded by non-genome dollars, e.g., GenBank, Protein Identification Resource, Bionet, DNA probe repository. This would release funds to the BIDs currently supporting these projects. OHGR is preparing an inventory of such projects and projected costs for the next few fiscal years. During the proposed transition, the Genome Center could take over management of existing resources as appropriate and, in particular, would be responsible for new resources that will need to be developed. Management of such resources is important to consider at the outset because it requires considerable staff time.

9. If the Center were to take over management of its own grants in the future, all aspects of grants management would have to be moved to the Center. Although the Center initially might share other overhead functions (personnel, budget) with another organizations, it is not feasible to share grants management services because these are so closely tied in with programmatic activities.

Annotated

First Meeting

PROGRAM ADVISORY COMMITTEE ON THE HUMAN GENOME

January 2, 3, and 4, 1989

PRELIMINARY AGENDA

Monday, January 2, 1989 — *Evening Session*

Bethesda Guest Quarters

6:00	Orientation Meeting for Advisory Committee Members	

Tuesday, January 3, 1989 — *Morning Session*

Building 31, C Wing, Conference Room 6

8:30	Opening Remarks and Charge to the Committee—history and definition of NIH genome program	*Dr. Wyngaarden*
8:45	Chairman's Remarks—dates of future meetings	*Dr. Zinder*
9:00	The Human Genome Project at NIH—background, goal, reason for	*Dr. Watson*
9:20	Function of Office of Human Genome Research—organization and coordination with other groups — go through table format	*Dr. Jordan*
9:30	Overview of Ongoing NIH Genome Activities	
20'	• National Institute of General Medical Sciences	*Dr. Kirschstein and staff*
20'	• National Library of Medicine	*Dr. Lindberg Dr. Masys and staff*
10:30	Coffee	

11:00 Key Genome—Related Resources Supported by NIH

10'	• GenBank—National Institute of General Medical Sciences	*Dr. Cassatt*
10'	• DNA Probe Repository and Chromosome Library—National Institute of Child Health and Human Development and Division of Research Resources	*Dr. Dayton*
10'	• Protein Identification Resource (PIR)—Division of Research Resources	*Dr. ~~Hirsch~~ Holloway*
10'	• Bionet—Division of Research Resources	*Dr. ~~Hirsch~~ Holloway*
10'	• Cell Bank—National Institute of General Medical Sciences	*Dr. Greenberg*

12:15 General Discussion

12:30 **Lunch**

Afternoon Session

1:30 Overview of Genome Activities in Other Agencies

20'	• U.S. Department of Energy—(including resources)	*Dr. Barnhardt*
20'	• Howard Hughes Medical Institute—(CEPH, HGML, OMIM)	*Dr. Cahill*
15'	• National Science Foundation	*Dr. Wooley*
15'	• U.S. Department of Agriculture	*Dr. Faust*

3:00 Coffee

3:30 International Activities

10'	• Human Genome Organization (HUGO)	*Dr. Watson* *Dr. McKusick*
10'	• Japan	*Dr. Olson*
10'	• United Kingdom	*Dr. Pearson*
	• Other	*Participants*

Tuesday, January 3, 1989 — *Afternoon Session* continued

4:30 General Discussion

5:00 Adjourn First Day

6:00 **Dinner** (sponsored by Howard Hughes Medical Institute) at the Cloisters

Wednesday, January 4, 1989 — *Morning Session*

8:30 Strategy for NIH:

A. Scope

- Biological
- Technical
- Division of Labor (other organizations)

B. Program Management

- Centers and R01s
- Grants and Contracts

C. Accessibility of Materials and Data

10:00 Coffee

10:30 C. Model Program

- Design
- Special Needs

D. Action Items

- Initiate Program
- Working Groups

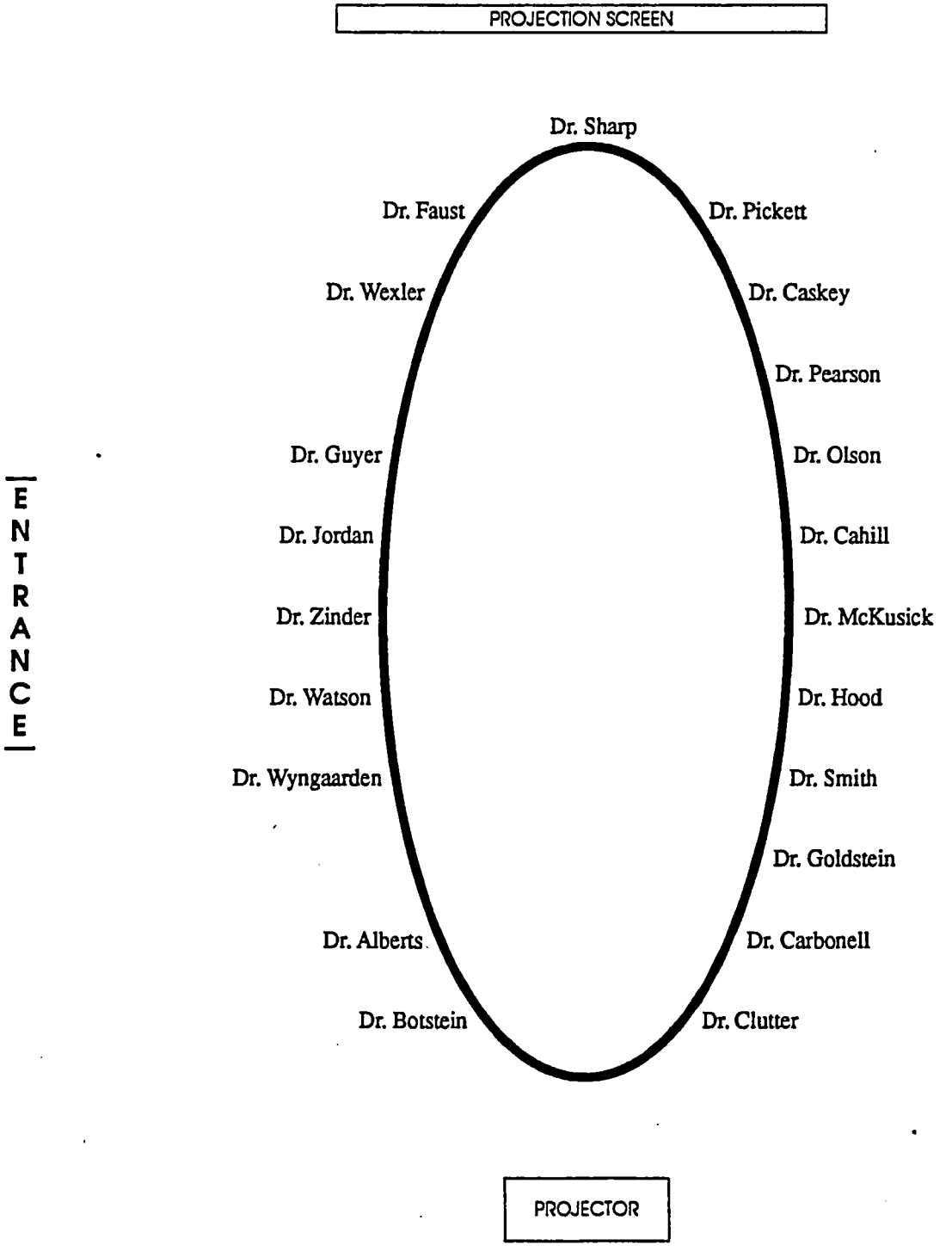
12:00 Summary

12:30 Adjournment — *Dr. Zinder*

First Meeting

Program Advisory Committee on the Human Genome

January 3 and 4, 1989
NIH, Building 31, C Wing, Conference Room 6



Plain

First Meeting

PROGRAM ADVISORY COMMITTEE ON THE HUMAN GENOME

January 3 and 4, 1989

PRELIMINARY AGENDA

Tuesday, January 3, 1989 — *Morning Session*

Building 31, C Wing, Conference Room 6

8:30	Opening Remarks and Charge to the Committee—history and definition of NIH genome program	*Dr. Wyngaarden*
8:45	Chairman's Remarks—dates of future meetings	*Dr. Zinder*
9:00	The Human Genome Project at NIH—background, goal, reason for	*Dr. Watson*
9:20	Function of Office of Human Genome Research—organization and coordination with other groups	*Dr. Jordan*
9:30	Overview of Ongoing NIH Genome Activities	
	• National Institute of General Medical Sciences	*Dr. Kirschstein and staff*
	• National Library of Medicine	*Dr. Lindberg Dr. Masys and staff*
10:30	Coffee	
11:00	Key Genome—Related Resources Supported by NIH	
	• GenBank—National Institute of General Medical Sciences	*Dr. Cassatt*
	• DNA Probe Repository and Chromosome Library—National Institute of Child Health and Human Development	*Dr. Dayton*

	• Protein Identification Resource (PIR)—Division of Research Resources	*Dr. ~~Hirsch~~ Holloway*
	• Bionet—Division of Research Resources	*Dr. ~~Hirsch~~ Holloway*
	• Cell Bank—National Institute of General Medical Sciences	*Dr. Greenberg*
12:15	General Discussion	
12:30	**Lunch**	

Afternoon Session

1:30	Overview of Genome Activities in Other Agencies	
	• U.S. Department of Energy—(including resources)	*Dr. Barnhardt*
	• Howard Hughes Medical Institute—(CEPH, HGML, OMIM)	*Dr. Cahill*
	• National Science Foundation	*Dr. Wooley*
	• U.S. Department of Agriculture	*Dr. Faust*
3:00	Coffee	
3:30	International Activities	
	• Human Genome Organization (HUGO)	*Dr. Watson* *Dr. McKusick*
	• Japan	*Dr. Olson*
	• United Kingdom	*Dr. Pearson*
	• Other	*Participants*
4:30	General Discussion	
5:00	Adjourn First Day	

8:30 Strategy for NIH:

A. Scope

- Biological
- Technical
- Division of Labor (other organizations)

B. Program Management

- Centers and R01s
- Grants and Contracts

C. Accessibility of Materials and Data

10:00 **Coffee**

10:30 C. Model Program

- Design
- Special Needs

D. Action Items

- Initiate Program
- Working Groups

12:00 Summary

12:30 Adjournment *Dr. Zinder*

Preliminary Roster

First Meeting

PROGRAM ADVISORY COMMITTEE ON THE HUMAN GENOME

January 3 and 4, 1989

Building 31, C Wing, Conference Room 6
National Institutes of Health
Bethesda, MD

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Preliminary List of Participants

First Meeting

PROGRAM ADVISORY COMMITTEE ON THE HUMAN GENOME

January 3 and 4, 1989

Building 31, C Wing, Conference Room 6
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Bethesda, MD

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OFFICE OF HUMAN GENOME RESEARCH

Administrative Plan

In recognition of the high priority placed on mapping and sequencing the human genome, and the overarching planning and resource demands of a systematic targeted effort, it is proposed that an Office of Human Genome Research be established within the Office of the Director, NIH. The function of the Office will be to provide coordination, integration, review of progress, and planning in genomic analysis research. Research goals and long-range plans will be formulated with the guidance of the NIH Program Advisory Committee on the Human Genome and the NIH ~~Working Group on the~~ Human Genome Coordinating Committee

Coordination Function

Given the current broad involvement in research related to the characterization of complex genomes, the essential coordination and integration function of the Office will span four areas:

- o Overall intra-agency NIH coordination;
- o Interagency coordination between NIH and other Federal agencies (DOE and NSF), and other research-funding organizations;
- o Collaboration with industry and academia; and
- o International cooperation.

The Office of Human Genome Research is envisioned as a new entity with a mandate to develop proposals for analysis of complex genomes. This strategy is not intended to supersede ongoing efforts within other NIH components, but to integrate those efforts into a cohesive plan. One goal will be to maximize the efficiency of information exchange regarding new mapping data, improved techniques for storage and handling of biological materiel, and enhanced data processing and analysis. Therefore, centralized coordination will rely heavily on effective interactions with BID programs, as well as with other research funding organizations and the academic research community.

The NIH Program Advisory Committee on the Human Genome

The NIH Program Advisory Committee on the Human Genome will be comprised of non-Federal employees with demonstrated expertise in the scientific disciplines related to genomic analysis. The Committee will advise the NIH on all aspects of genomic analysis. The Committee will identify opportunities to further advance characterization of the genetic material of many organisms. The Committee will also recommend initiatives that should be undertaken to promote the development of new technologies that will lead to a deeper understanding of molecular biology. The Committee will also advise on research directions and identify areas of research requiring additional effort. The Committee will propose administrative solutions to the resource and training needs of the research community, specific to genomic analysis.

Of necessity, the membership of the NIH Program Advisory Committee on the Human Genome will represent a number of diverse research disciplines including, but not limited to, molecular genetics, physical chemistry, bioengineering, mathematics, and computer science.

The Office of Human Genome Research

The Office of Human Genome Research will serve as a focus within NIH and with other components of Public Health Service, reviewing policy questions, and coordinating plans for future research efforts. The Office will play an important role in exchanging information on the scientific activities in the Intramural Research Program. The Office will provide an internal framework for the review and consideration of a number of issues requiring the viewpoint of the biomedical research community.

Leadership for this initiative will be provided by the NIH Associate Director for Human Genome Research. This position will be held by a distinguished scientist who will be expected to remain current in his/her discipline. One means for recruiting such an individual would be to classify the position as part-time, offering the opportunity to maintain an ongoing research program. The Director of the Office of Human Genome Research will be responsible for day-to-day administrative operations in accordance with the guidance of the Associate Director.

The Office of Human Genome Research will develop a plan for a centralized, systematic, targeted effort to create detailed maps of the genomes of several organisms. The precise order and choice of goals would be determined with the advice of the Program Advisory Committee, but examples might include yeast, Drosophila, Caenorhabditis elegans, mouse, and human genomes.

The Office of Human Genome Research will not have a research budget to fund new initiatives. These initiatives will be supported by the BIDs and will pay particular attention to interdisciplinary projects that may not have a traditional locus in one BID. In addition, the coordination function of the Office will facilitate multiple Institute support for suitable proposals.

All grants and contracts funded as part of the genome program will be approved in accordance with traditional NIH peer review procedures.