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Collection/Office of Origin: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: General Science Files

OA/ID Number: 62038
Folder ID Number: 62038-005

Folder Title:
Life Sciences: General [1 of 7] [1992]

Stack:

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"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203649
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: *Fukui, Yoshio*
~~COLLINS, Christine~~: NORTHWESTERN UNIVERSITY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/21/92

SUBJECT: SHE IS WRITING TO SOLICIT DR. BROMLEY'S ASSISTANCE
IN ENSURING THE CONTINUED PARTICIPATION OF NIH IN
THE FEDERAL DEMONSTRATION PROJECT.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED: Margaret Quinlan

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: Necessary Action

SENDER'S DUE DATE:
OSTP DUE DATE: 01/08/93 STAFF DUE DATE 01/08/93
DATE COMPLETED: DATE COMPLETED/DEPT: 01/07/93

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: Dr. Collins wrote an identical letter to Dr. Raub, which arrived
after his departure from OSTP. Dr. Henderson responded to
Collins on 12/30/92; therefore, another response is not
necessary. Close record.



OSTP RECEIVED: 12/28/92 DEPT RECEIVED: 01/07/93
FILE: P-LIFE SCIENCES

CENTRAL FILES:

Northwestern University Medical School



Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 21, 1992

D. Allen Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
Room 358
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Bromely:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with the President's January 28, 1992 Memorandum for Certain Department Agency Heads on the subject of "Reducing the Burden of Government Regulations".

As you may know, the FDP was initiated in 1988 to help eliminate unnecessary administrative burdens on sponsored research and thereby enhance the research productivity of the United States. The noncompeting continuation pilot of the Federal Demonstration Project, initiated July 15, 1990, allowed participating federal agencies to issue out year funding commitments based upon an annual progress report. Some of the participating agencies, due to legal requirements or major procedural disruption, continued the requirement for a cover page. Other documentation was required only if significant changes occurred in the size or scope of a project.

A recent survey of the 1,092 researchers impacted by the noncompeting application process perhaps best demonstrates its importance. Overall, 1092 researchers reported time savings of 2.26 days under the noncompeting continuation demonstration of the FDP. Collectively, researchers saved 2464 days, with 90 percent of those days reinvested to scholarly activities. To provide another perspective on these "time reinvestments", it can be said that the study documents a total of 8.5 person-

years of additional scholarly activities. Further applying these rates of return, it is possible to project that the overall additional investment in research activity made possible by FDP was roughly eighteen person years of research.

I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Yoshio Fukui', with a long horizontal flourish extending to the right.

Yoshio Fukui, Ph.D.
Associate Professor

"Document Control"

TYPE: ACTION DOCUMENT NUMBER: 9203649
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS

FROM: COLLINS, Christine: NORTHWESTERN UNIVERSITY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/21/92

SUBJECT: SHE IS WRITING TO SOLICIT DR. BROMLEY'S ASSISTANCE
IN ENSURING THE CONTINUED PARTICIPATION OF NIH IN
THE FEDERAL DEMONSTRATION PROJECT.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 01/08/93 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS:

OSTP RECEIVED: 12/28/92 DEPT RECEIVED:
FILE: P-LIFE SCIENCES
CENTRAL FILES:

Northwestern University Medical School



Department of Cell, Molecular,
and Structural Biology

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303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 21, 1992

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Assistant to the President for Science and Technology
Old Executive Office Building
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Washington, DC 20500

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I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in blue ink that reads "Christine Collins". The signature is written in a cursive style with a large, flowing "C" at the beginning.

Christine Collins, Ph.D.
Assistant Professor

"Document Control"

TYPE: ACTION DOCUMENT NUMBER: 9203665
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS

FROM: WATKINS, James D.: U.S. SECRETARY OF ENERGY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/28/92

SUBJECT: HE IS WRITING REGARDING THE HUMAN FRONTIER SCIENCE
PROGRAM.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 01/15/93 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

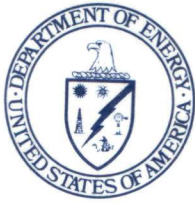
COPIES TO: D. Allan Bromley
PHYSICAL SCIENCES

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 12/31/92 DEPT RECEIVED:
FILE: P-LIFE SCIENCES

CENTRAL FILES:

3665



The Secretary of Energy
Washington, DC 20585

December 28, 1992

The Honorable D. Allan Bromley
Assistant to the President
for Science and Technology
The Old Executive Office Building
Room 360
Washington, D.C. 20506

Dear Dr. ^{Allan} Bromley:

Thank you for your memorandum of November 24, 1992, concerning the U.S. contribution to the Human Frontier Science Program (HFSP). The Department of Energy (DOE) stands ready to meet its FY 1993 commitment to the HFSP.

I endorse your suggestion that DOE, the National Institutes of Health, and the National Aeronautics and Space Administration make their contributions by transferring funds to the National Science Foundation (NSF) which would then, on behalf of the U.S., provide the HFSP with the total U.S. contribution. We are prepared to transfer the agreed-upon sum of \$1 million to the NSF. Please have your office contact Dr. David J. Galas, Associate Director for Health and Environmental Research, Office of Energy Research, at (301) 903-3251 to make the necessary arrangements.

Sincerely,


James D. Watkins
Admiral, U.S. Navy (Retired)

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203684
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: DECKER, Robert S.: NORTHWESTERN UNIVERSITY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/21/92

SUBJECT: HE IS WRITING TO SOLICIT DR. BROMLEY'S ASSISTANCE IN
ENSURING THE CONTINUED PARTICIPATION OF THE NATIONAL
INSTITUTES OF HEALTH IN THE FEDERAL DEMONSTRATION
PROJECT.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: AS NECESSARY

SENDER'S DUE DATE:
OSTP DUE DATE: 01/15/93 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT: 01/13/93

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: An identical letter was sent to Dr. Raub, which was answered by
Dr. Henderson. Therefore, action has been completed and the
document can to be closed out. (dic)

OSTP RECEIVED: 01/11/93
FILE: P-LIFE SCIENCES

DEPT RECEIVED: 01/13/93

CENTRAL FILES:



3684

Northwestern University Medical School



Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
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(312) 503-8250
Fax (312) 503-7912/4516

December 21, 1992

D. Allen Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
Room 358
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

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years of additional scholarly activities. Further applying these rates of return, it is possible to project that the overall additional investment in research activity made possible by FDP was roughly eighteen person years of research.

I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in blue ink, appearing to read "R. Decker", with a stylized flourish at the end.

Robert S. Decker, Ph.D.
Professor

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203624
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: SALTIKOV, B.G.: MINISTER OF SCIENCE AND HIGHER EDUCATION,
RUSSIAN FEDERATION

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/17/92

SUBJECT: HE IS NAMING CANDIDATES TO CONTRIBUTE TO OTA'S STUDY
"THE HUMAN GENOME AND PATENTING HUMAN DNA SEQUENCES.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED: Clifford J. Gabriel

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: AS NECESSARY

SENDER'S DUE DATE:
OSTP DUE DATE: 12/31/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT: 12/23/92

COPIES TO: D. Allan Bromley
INTERNATIONAL/POLICY
John O'Neil

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS:



OSTP RECEIVED: 12/18/92 DEPT RECEIVED: 12/23/92
FILE: P-LIFE SCIENCES

CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

December 23, 1992

Boris
Dear Minister Saltykov:

Thank you for submitting the names of A. A. Baev, A.D. Mirzabekov and B. K. Kaloshin as potential contacts from the Russian Federation for the OTA project on patenting human DNA sequences. I have forwarded this information to Dr. Robyn Nashimi, OTA Project Director for this activity.

Sincerely yours,

Alan
D. Allan Bromley
The Assistant to the President
for
Science and Technology

The Honorable B. G. Saltykov
Minister for Science, Higher Education
and Technology Policy
Russian Federation
Moscow, Russia

*As the best in the new year
I regret that I will not be able to
continue working with you.
DAB*

1

unofficial translation

D. Allan BROMLEY
The Assistant to the President
for Science and Technology

The White House,
Washington D.C. 20506
U.S.A.

December 17, 1992.

Dear Dr. Bromley,

In connection with Your kind suggestion on possible participation of the Russian specialists as consultants in the project of the Congressional Office of Technology Assessment "The Human Genome and Patenting Human DNA Sequences" we consider expedient to recommend candidatures of the Chairman of the Scientific Council of the State Science Program in Russia "Human Genome" academician of the Russian Academy of Science A.A.BAEV, his deputy academician A.D. MIRZABEKOV and doctor B.K.KALOSHIN, Deputy Director of the Department of Science on Life and Biotechnology of the Ministry for Science, Higher Education and Technology Policy of the Russian Federation.

We believe that the above mentioned specialists will be able to contribute to development of these important scientific issues.

Sincerely,

Dr.B.G.Saltikov
Minister of Science, Higher Education
and Technology Policy
of
Russian Federation



**МИНИСТЕРСТВО НАУКИ, ВЫСШЕЙ ШКОЛЫ
И ТЕХНИЧЕСКОЙ ПОЛИТИКИ РОССИЙСКОЙ
ФЕДЕРАЦИИ**

М И Н И С Т Р

103905, Москва, ул. Таверская, 11
Тел. 229-11-92 Телетайп 417531 „Триод“

от _____ № _____

на № _____

**Доктору Д.Аллану БРОМЛИ
Советнику Президента США
по науке и технике**

**Белый Дом, Вашингтон Д.С.
США**

17 декабря 1992г.

Уважаемый доктор Бромли!

В связи с Вашим предложением относительно возможного участия российских специалистов в проекте Оффиса Конгресса по Оценке Технологий в качестве консультантов по вопросу о патентовании генов и их фрагментов полагали бы целесообразным рекомендовать кандидатуры Председателя Научного Совета Государственной научно-технической программы России "Геном человека" академика Российской Академии наук А.А.БАЕВА; его заместителя академика Российской Академии наук А.Д.МИРЗАБЕКОВА и доктора Б.К.КАЛОШИНА, заместителя начальника Управления наук о жизни и биотехнологии Министерства науки, высшей школы и технической политики Российской Федерации.

Надеюсь, что рекомендуемые специалисты смогут внести свой вклад в разработку этих важных научных вопросов.

С уважением,

Б.Г.САЛТЫКОВ

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203633
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: LaPORTE, Ronald E.: UNIVERSITY OF PITTSBURGH

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/15/92

SUBJECT: HE IS WRITING REGARDING COLLABORATIVE WORK WITH
RUSSIA ON CHILDHOOD DIABETES.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED: D.A. Henderson

ACTION STAFF
REQUIRED: FOR DAB'S SIGNATURE ACTION: Bromley Signature

SENDER'S DUE DATE:
OSTP DUE DATE: 01/04/93 STAFF DUE DATE 01/04/93
DATE COMPLETED: DATE COMPLETED/DEPT: 12/29/92

COPIES TO: D. Allan Bromley
INTERNATIONAL/POLICY

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 12/23/92
FILE: P-LIFE SCIENCES

DEPT RECEIVED: 12/28/92

CENTRAL FILES:



THE WHITE HOUSE

WASHINGTON

December 29, 1992

Dear Dr. LaPorte,

Thank you for your recent letter and its enclosures, regarding your varied and collaborative efforts with scientists in Russia. I appreciate receiving this information and assure you it will be of value. Thank you as well, for referring Dr. Dorman to this office as a future point of contact.

You seem to be on the right track, both with your efforts in childhood diabetes mortality and also with your initiatives in computer based telecommunications networking. I am pleased to see that the Fogarty International Center is assisting you in your endeavors.

I share your enthusiasm of recognizing scientists who actively and altruistically collaborate only for science's sake -- it is indeed admirable. Thank you for your offer of advice; I may call upon your expertise should the need arise.

Sincerely yours,

A handwritten signature in dark ink, reading "D. Allan Bromley". The signature is fluid and cursive, with a large, sweeping initial "D".

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Ronald E. LaPorte, Ph.D.
Director
WHO Collaborating Center for Diabetes Registries and Training

Professor
Department of Epidemiology
Graduate School of Public Health
University of Pittsburgh
Pittsburgh, Pennsylvania 15261



University of Pittsburgh

GRADUATE SCHOOL OF PUBLIC HEALTH
Department of Epidemiology

December 15, 1992

Dr. D. Allan Bromley
U. S. President Scientific Advisor
Executive Office
Washington, DC 20506

Dear Dr. Bromley,

Dr. Philip Chen contacted me concerning collaborative work being established with Russia. We have developed a strong and effective collaboration between Russian and our WHO Collaborating Center for Childhood Diabetes. The Russians have joined the collaboration with no funding.

I have enclosed an overview of the WHO DiaMond project that we are coordinating. In addition, I have included a description of the present two centers in the program. The group in Moscow is the leading endocrinology group in Russia. They are currently expanding the WHO DiaMond project to numerous sites in Russia, including Eastern Russia.

A second area that we have developed with the Russians is that of computer based telecommunications. We were one of the first medical research groups to network into Russia, both Moscow and Siberia, using computer networking. The Russians have completed supported the effort on their side; we provide no support to them.

As our collaboration with Moscow has become strong and stable, we have applied for a small grant to Fogarty to add a Russian center to our NIH funded NIH study on childhood diabetes mortality. Enclosed is the abstract. Also, we received a small grant from Fogarty to begin discussions about how to establish a joint U.S.-Russia diabetes epidemiology training program.

Dr. Janice Dorman who heads our molecular epidemiology section also has extensive links with the Russians not only on the above project but in the area of molecular epidemiology. She will shortly be contacting you.

PITTSBURGH, PA 15261 USA (412) 692-5200 TELEFAX: (412) 692-8329 TELEX: 199126



World Health Organization
Collaborating Center for Diabetes Registries, Research and Training

December 15, 1992

Page 2

We have found a group of very motivated scientists who want to collaborate because of the science; not to become rich. Please let us know if we can give you any advice.

Sincerely yours,



Ronald E. LaPorte, Ph.D.
Director, WHO Collaborating Center
for Diabetes Registries and Training

Professor, Department of Epidemiology

REL/eam

METHODS OF OPERATION FOR THE SIBERIAN IDDM REGISTRY

NOTE: SIBERIAN IDDM REGISTRY CONSIST OF

1. Novosibirsk City IDDM Registry: code [1] in 7 column of Incidence Data Reporting Form and code [1] in Population Demographics Reporting Form (including only Novosibirsk City's children)

2. Novosibirsk Area IDDM Registry: code [2] in 7 column of Incidence Data Reporting Form and code [2] in Population Demographics Reporting Form (including all children from Novosibirsk Region without Novosibirsk City's children)

1. POPULATION DATE

1. Administrative description of the region.

Novosibirsk region is an administrative unit of Russia. The most of its territory is situated on West-Siberian plain. And only in the eastern part of it one can see some mountains, for example Salairsky Kryazh. The main river is Ob. Annual precipitation - 300-450 mm. Annual mean air temperature - 0 C. The territory makes up 178 300 square kilometres. The center of the region is Novosibirsk City. The city covers the territory of 477 square kilometres. Novosibirsk City is a large industrial center on the bank of Ob-river and Ob artificial sea.

2. Sources and quality of population data.

In 1989 the census of population of Novosibirsk region was conducted. On the basis of census data and annual registration of people (born, dead and migrants), the Novosibirsk department of the USSR Central Statistical Office has created quantitative structure of regional population (separately for Novosibirsk City's children and for children from other parts of Novosibirsk Region).

3. Size of the population and distribution according to sex and nationality.

In 1989 the population of the region was 2 778 724 and 645 355 of them-under 15 years of age. Novosibirsk City population in 1989 was 1 435 889, under 15 years - 305 508. National composition of the population is presented in table 1 (according to the 1989 census data).

TABLE 1. Distribution according to nationality (%).

	Russians	Ukrainians	Germans
Novosibirsk City	93	2,0	1,3
Novosibirsk Region	92	2,2	1,8

Distribution according to sex and age is presented in tables 2 and 3 (according to the 1989 census data).

TABLE 2. Distribution of Novosibirsk Region children according to sex and age.

Age	Girls	Boys
0 - 4	109 085	104 357
5 - 9	111 280	114 100
10 - 14	101 368	104 165

TABLE 3. Distribution of Novosibirsk City children according to age and sex.

Age	Girls	Boys
0 - 4	51 351	53 863
5 - 9	50 506	52 423
10 - 14	47 861	49 504

4. Population stability assessment.

In 1989 about 4% of population left the cities of Novosibirsk region, and about 4,5% of total urban population arrived there. The most of migration is intraregional. According to our data the share of migration between the regions is within 2% of the total number of migrants. Average increase of children population for the period of 1979 - 1989 (1989 in % comparing to 1989) is presented in table 4.

TABLE 4. The increase of children population since 1979 up to 1989 in % (Novosibirsk region).

Age	Girls	Boys
0 - 4	105,1	106,8
5 - 9	123,5	122,2
10 - 14	119,4	118,7

2. REGISTER STRUCTURE

1. Organizational structure

The register of IDDM is formed by the research-workers of Institute of Internal Medicine, Novosibirsk. The director of the Institute is professor Yu.P.Nikitin.

The responsible investigator on the register - Dr.E.V.Shubnikov.

2. Case identification.

Case identification is based on:

- retrospective review of medical documentation of 2 endocrinological departments of Novosibirsk, where the children (from whole Novosibirsk region) with suspected and revealed IDDM is admitted for initial diagnostic and treatment. The case reports of these two hospital departments are the primary sources of data for our register. In course of 1 year a person in charge for the information collection will study all the case reports. And if he comes across a newly revealed disease he ought to register all the data on this child.

- retrospective review of children endocrinologist data performing the control of ambulatory children with IDDM, consulting children with suspected IDDM, revealing children with IDDM with subsequent hospitalization in one of 2 endocrinological departments. This is the secondary sources of register data. Once per year our research-worker is going to visit each of children endocrinologists to compare the number of patients with the number of those controlled by children endocrinologist. If there appears the patient who has not obtained the hospitalized treatment, he will also have his registration form filled.

Thus the secondary data source is not completely independent of the primary one because of the system of medical care in Russia.

We plan the prospective study of children with IDDM with direct data collection at a sick-bed in 2 endocrinological departments of the city (with newly revealed IDDM).

Investigator in charge for case identification - Dr.L.A.Kalashnikova.

3. The reliability of the study.

The definition of primary source reliability will be conducted annually by the procedure described in "DIAMOND" Methods of Operation. During the period of 1983 - 1990 we have conducted the study of completeness of IDDM cases revealing in children of Novosibirsk. Using method of capture-recapture we found out that the completeness of IDDM revealing made up 95% for the primary source and 72% for the secondary source. Unfortunately, we have not got the secondary source for the children of Novosibirsk area, so far.

3. DATA MANAGEMENT

1. Minimum data for the registration.

1. Name
2. Sex
3. Nationality
4. Date of birth
5. Date of diagnosis
6. Date of the first insulin injection
7. The adress on the moment of revealing
8. Age (full years) on the moment of revealing
9. Data on hospitalizations
10. Source of identification (or sources)

2. Schedule of works on the register.

The data collection for the previous year will be finished by June of the current year. The data on the quantitative composition of children population are usually available since November of the next year. By December the data will be transferred to the data Center.

3. Data introduction, storage and transfer.

The data will be introduced by programs presented by Data Center in Pittsburg. Data will be stored both in computer (on soft discettes) and in printed form. Data processing for local use and data transfer to the Data Center will be performed on IBM Computer on program discettes which were worked out in Pittsburg Center and are used now in all DIAMOND Centers.

Responsible for data transfer is Dr.E.V.Shubnikov.

РУКОВОДСТВО К ДЕЙСТВИЯМ, В РАМКАХ ПРОГРАММЫ "ДИАМОНД", НОВО-СИБИРСКОГО РЕГИСТРА ИЗСД/инсулин-зависимого сахарного диабета/

Заметка: Сибирский регистр ИЗСД состоит из

1. Регистра ИЗСД детей г.Новосибирска: кодируется 1 в 7 колонке отчетной формы по заболеваемости и 1 в отчетной форме демографических данных (включает только детей города Новосибирска).

2. Регистра ИЗСД детей Новосибирской области: кодируется 2 в 7 колонке отчетной формы по заболеваемости и 2 в отчетной форме демографических данных (включает только детей Новосибирской области).

1. ПОПУЛЯЦИОННЫЕ ДАННЫЕ

1. Административное описание области.

Новосибирская область — административная единица России. Большинство территории области расположено на Западно-Сибирской равнине, лишь на востоке встречаются небольшие горы, например Салаирский кряж. Главная река Обь. Осадков 300–450 мм в год. Среднегодовая температура воздуха около 0 градусов по Цельсию. Территория области составляет 178 300 км.кв. Центр области город Новосибирск. Площадь города 477 км.кв. Город является крупным промышленным центром на берегу Оби и Обского водохранилища.

2. Источник и качество популяционных данных.

Новосибирское отделение Центрального статистического Управления СССР располагает и выдает данные по численному составу лиц, проживающих в Новосибирской области, на основе переписей населения, последняя из которых произведена в 1989 году и данных учета других демографических процессов (рождаемость, смертность и миграция).

3. Размер популяции, распределение по половой, национальной принадлежности.

В 1989 году в области проживало 2 778 724 человек, из них до 15 лет 654 355 человек. Население города Новосибирска в 1989 году было 1 435 889, из них до 15 лет 305 508 человек. Национальный состав представлен в таблице 1./по данным переписи 1989 года/.

Таблица 1. Распределение по национальному составу в процентах

	Русские	Украинцы	Немцы
г.Новосибирск	93%	2%	1,3%
Новосибирская область	92%	2,2	1,8

Распределение по половому и возрастному признаку представлены в таблице 2 и 3./по данным переписи 1989 года/

Таблица 2. Распределение по половому и возрастному признаку детей Новосибирской области.

возраст	девочки	мальчики
< 5	109 085	104 357
5-9	111 280	114 100
10-14	101 368	104 165

Таблица 3. Распределение по половому и возрастному признаку детей г.Новосибирска

возраст	девочки	мальчики
< 5	51 351	53 863
5-9	50 506	52 423
10-14	47 861	49 504

4. Оценка стабильности популяции.

В 1988 году из городов Новосибирской области выехало около 4% населения, прибыло около 4,5% от числа городских жителей. Большая часть миграции является внутриобластной. По нашим данным процент межобластной миграции не превышает 2% от всего количества меняющих место жительства. В среднем за период 1979-1989 годов увеличение детского населения в 1989 году в % к 1979 году отражено в таблице 4.

Таблица 3. Увеличение численности детского населения с 1979 по 1989 год в процентах

Возраст	девочки	мальчики
<5	105,1	106,8
5-9	123,5	122,2
10-14	119,4	118,7

2. СТРУКТУРА РЕГИСТРА

1. Организационная структура.

Регистр ИЗСД сформирован из сотрудников Института терапии, находящегося в г.Новосибирске. Директор Института-академик АМН СССР Ю.П.Никитин.

Ответственный исполнитель работ по регистру: Шубников Е.В.

2. Идентификация случаев.

Идентификация случаев базируется на:

-Ретроспективном обзоре медицинской документации 2 эндокринологических отделений г. Новосибирска, куда госпитализируются все дети из Новосибирской области с подозрением на ИЗСД, или с выявленным ИЗСД для начальной диагностики и лечения. Первичным источником данных нашего регистра являются истории болезни этих 2 отделений. В течение года, сотрудник, ответственный за сбор информации будет производить просмотр всех историй болезни и в случае впервые выявленного заболевания регистрировать все данные на заболевшего ребенка.

-Ретроспективный обзор данных детских эндокринологов, ведущих амбулаторный прием и, осуществляющих: наблюдение за детьми с ИЗСД, консультирование детей с подозрением на ИЗСД, выявление у детей ИЗСД с последующей госпитализацией в одно из двух эндокринологических отделений. Это вторичный источник регистра. Один раз в год сотрудник регистра будет посещать каждого из детских эндокринологов для сверки имеющегося числа больных с наблюдающимися у детского эндокринолога. В случае наличия на учете больного, не прошедшего стационарного лечения, на него будет также заполняться карта регистра.

Таким образом вторичный источник данных не является полностью независимым от первичного в силу сложившейся системы оказания медицинской помощи в России.

Планируется проспективное наблюдение детей с ИЗСД путем непосредственного сбора информации у постели больного, с впервые выявленным ИЗСД, в 2 эндокринологических отделениях города.

Ответственный за идентификацию случаев: Калашникова Л.А.

3. Достоверность исследований.

Определение достоверности первичного источника будет производиться ежегодно с использованием процедуры, описанной в Методах действий для всей программы "Диамонд". За период 1983-1990 годов нами проведено изучение полноты определения случаев ИЗСД у детей г.Новосибирска. Используя метод капче-рекапче, полнота выявления ИЗСД составила 95% для первичного источника, 72% вторичного источника. Для детей Новосибирской области мы, к сожалению, не имеем вторичного источника, пока.

3. УПРАВЛЕНИЕ ДАННЫМ

1. Минимум данных, подлежащих регистрации

1. ФИО.
2. Пол.
3. Национальность.
4. Дата рождения.

5. Дата диагностики.
6. Дата первого применения инсулина.
7. Адрес на момент выявления.
8. Число лет в момент выявления.
9. Данные о госпитализациях.
10. Источник или источники идентификации.

2. Расписание работ по регистру

Сбор данных за прошедший год будет завершаться к июню текущего года. Данные по количественному составу детского населения обычно доступны с ноября месяца последующего года. Таким образом данные по заболеваемости и по количеству населения могут быть введены в компьютер в ноябре месяце последующего года за отчетным. К декабрю данные будут переведены в центр обработки данных.

3. Ввод данных, хранение, передача.

Данные будут вводиться по программам, представленным центром обработки данных в Питтсбурге. Хранение данных будет осуществляться как в компьютере (на мягких дисках), так и в распечатанном виде. Обработка данных для местного использования и перевод данных в центр обработки данных будет осуществлен с помощью ИБМ компьютера и дискет по программе специально разработанной в Питтсбургском центре и используемой для всех центров Диамонд.

Ответственность за перевод данных несет Шубников Е.В.

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
01. Form	Page 2 of grant application [personal information redacted] (1 pp.)	12/22/92	(b)(6)	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: General Science Files
WHORM Cat.:
File Location: Life Sciences: General [1 of 7] [1992]

Date Closed:	3/15/2010	OA/ID Number:	62038-005
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

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P-1 National Security Classified Information [(a)(1) of the PRA]
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P-4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P-5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P-6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

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(b)(1) National security classified information [(b)(1) of the FOIA]
(b)(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
(b)(3) Release would violate a Federal statute [(b)(3) of the FOIA]
(b)(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
(b)(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
(b)(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
(b)(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
(b)(9) Release would disclose geological or geophysical information

AUTOMATIC COVER SHEET

DATE: DEC-22-92 TUE 20:13

TO:

FAX #: 92023953261

FROM: DIABETES RESEARCH CENTER

FAX #: 4126928329

12 PAGES WERE SENT

(INCLUDING THIS COVER PAGE)

"Document Control"

TYPE: INFORMATION

DOCUMENT NUMBER: 9203627

ORIGINATOR: 02

STATUS C

DIRECTORATE STATUS

FROM: SCHROETER, Klaus: SCIENCE COUNSELOR, GERMAN EMBASSY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/14/92

SUBJECT: HE IS FORWARDING A COPY OF HIS LETTER TO DR. BROMLEY
REGARDING THE STUDY ON PATENTING THE HUMAN DNA
SEQUENCES.

DIRECTORATE STAFF
ASSIGNED: ASSIGNED:

ACTION STAFF
REQUIRED: ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: INTERNATIONAL/POLICY

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS:

OSTP RECEIVED: 12/18/92
FILE: P-LIFE SCIENCES

DEPT RECEIVED:

CENTRAL FILES:

Botschaft
der Bundesrepublik Deutschland
Embassy
of the Federal Republic of Germany
Letter Ref.#: Wiss 469.32

Washington, December 14, 1992

The Honorable
Dr. Donald H. Henderson
Associate Director for
Life Sciences
Office of Science and
Technology Policy
Old Executive Bldg.
Room 494
Washington, DC 20500

Subject: Study on Patenting Human DNA-Sequenzen

Dear Dr. Henderson:

You suggested the participation of German experts in a Study on Patenting Human DNA-Sequenzen now to be carried out by the Office of Technology Assessment.

I am glad to be able to inform you that the we would like to offer the active cooperation of the two following experts:

Prof. Dr. Joseph Straus
Max-Planck-Institut für
ausländisches und internationales
Patent-, Urheber- und Wettbewerbs-
recht
(Foreign and international Patent Law,
Copyright and Competition Law)
Siebertstr. 3
D-8000 München 80
Tel.: 011-49-89-90 24 63 73
Fax.: 011-49-89-90 24 62 47

Prof. Dr. med. Walter Dorfler
Universität Köln
Weyertal 121
D-5000 Köln 41
Tel.: 011-49-221-4 70 23 86
Fax.: 011-49-221-4 70 51 63.

I appreciate if OSTP would support their participation in the envisaged OTA Study. I informed Dr. Roger Herdman, Assistant Director of OTA and the OTA Project Leader Dr. Robyn Nishimi about the German offer and I got already their principle consent for the participation of the two German experts.

Thank you very much for your suggestion. Let's hope we achieve a constructive result.

Merry Christmas and all good wishes for The New Year.

Kind regards



Dr. Klaus Schroeter
(Science Counselor)

CC: The Honorable Dr. D. Allan Bromley, Science Advisor to the President and President of the Office of Science and Technology Policy

CC: The Honorable Dr. Thomas Ratchford, Associate Director, Office of Science and Technology Policy

May

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203585
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: SHORE, Bill: SOS

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/10/92

SUBJECT: HE IS WRITING TO ASK FOR DR. BROMLEY'S SUPPORT OF
THEIR ANTI-POVERTY EFFORTS.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED: D.A. Henderson

ACTION STAFF
REQUIRED: AS/IF NECESSARY ACTION: Necessary Action

SENDER'S DUE DATE:
OSTP DUE DATE: 12/28/92 STAFF DUE DATE 12/28/92
DATE COMPLETED: DATE COMPLETED/DEPT: 12/18/92

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: Per D.A., no reply is necessary. Especially because any reply is
apt to be exerpted into a quote for the publication.



OSTP RECEIVED: 12/14/92 DEPT RECEIVED: 12/18/92
FILE: P-LIFE SCIENCES

CENTRAL FILES:

TYPE: ACTION

DOCUMENT NUMBER: 9203585

ORIGINATOR: 02

STATUS I

DIRECTORATE STATUS

FROM: SHORE, Bill: SOS

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/10/92

SUBJECT: HE IS WRITING TO ASK FOR DR. BROMLEY'S SUPPORT OF
THEIR ANTI-POVERTY EFFORTS.

DIRECTORATE

STAFF

ASSIGNED: LIFE SCIENCES

ASSIGNED:

ACTION

STAFF

REQUIRED: AS/IF NECESSARY

ACTION:

SENDER'S DUE DATE:

OSTP DUE DATE: 12/28/92

STAFF DUE DATE

DATE COMPLETED:

DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #:

CONTACT PERSON:

PHONE:

EXT:

REMARKS:

OSTP RECEIVED: 12/14/92

DEPT RECEIVED:

FILE: P-LIFE SCIENCES

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Steven Rivers, Creative Artists Agency
Jimmy Schmidt, The Rattlesnake Club
Bill Shore, Share Our Strength

December 10, 1992

Dr. Allan Bromley
Presidential Science Advisor
The White House
Washington, D.C. 20500

Dear Dr. Bromley:

In light of your work with scientists and science educators, I wanted to call your attention to a new anthology of science essays which I edited called *Mysteries of Life and the Universe*, just published by Harcourt Brace Jovanovich. Proceeds from book sales will benefit Share Our Strength and the National Commission to Prevent Infant Mortality.

Already, *Mysteries of Life and the Universe* has received abundant praise from critics. Kirkus Reviews says: "It's been a long time since such a fine science anthology came into view... there's something for everyone and everything for those who love science." I've enclosed several reviews and a press packet on the book.

I am writing to ask that you join us in raising awareness of this project and its beneficiaries. Specifically, it is our hope that you will consider mentioning the book in any magazine, journal, or newsletter which your organization produces.

Over the past four years Share Our Strength has sought to bring writers, and important community causes together through its unique anthologies whose proceeds are used to fund anti-poverty efforts. *Mysteries of Life and the Universe* is the latest anthology, containing science essays for a general readership by twenty-nine of the country's best science writers. It follows two volumes of short fiction called *Louder Than Words* and *Voices Louder Than Words*, and a children's book called *Home*. In all cases the authors donated original manuscripts so that book proceeds could benefit Share Our Strength's programs fighting hunger, homelessness, and illiteracy.

If you would like further information about Share Our Strength or our book projects, please do not hesitate to contact me at (202) 393-2925.

Sincerely,

Bill Shore
Executive Director

Enclosures

COURT
ACE
OVICH

DIANE ACKERMAN
ANTHONY AVENI
MICHAEL H. BROWN
JAMES O. FARLOW
TIMOTHY FERRIS
DAVID H. FREEDMAN
MARTIN GARDNER
JAMES GORMAN
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JUDITH STONE
JAMES TREFIL
HANS CHRISTIAN VON BAEYER
ROBERT WRIGHT
A. ZEE



Mysteries

NEW ESSAYS FROM

of Life

AMERICA'S FINEST

and the

WRITERS ON SCIENCE

U niverse

EDITED BY

WILLIAM H. SHORE

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203576
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: BARTLES, James: NORTHWESTERN UNIVERSITY MEDICAL SCHOOL

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/09/92

SUBJECT: HE IS WRITING TO SEEK DR. BROMLEY'S ASSISTANCE IN
ENSURING THE CONTINUED PARTICIPATION OF NIH IN THE
FEDERAL DEMONSTRATION PROGRAM.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: AS NECESSARY

SENDER'S DUE DATE:
OSTP DUE DATE: 12/28/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT: 12/17/92

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: An identical letter was sent to Bill Raub which was answered by
Dr. Henderson; therefore, the item has been handled for OSTP and
no additional action is needed. (donna - see attachment)

OSTP RECEIVED: 12/14/92 DEPT RECEIVED: 12/17/92
FILE: P-LIFE SCIENCES

CENTRAL FILES:



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

December 14, 1992

Dear Dr. Bartles:

Thank you for your letter to Dr. William F. Raub regarding the decision by the National Institutes of Health (NIH) to discontinue its participation in one of the activities of the Federal Demonstration Project (FDP), i.e., the trial of a simplified application procedure for noncompeting continuation grants. Dr. Raub is no longer with the Office of Science and Technology Policy so I am replying to your inquiry. Your disappointment at this turn of events is understandable, for the procedures by which agencies of the federal government handle noncompeting renewal awards undoubtedly include unnecessary and unproductive administrative requirements and therefore are an appropriate focus for an FDP initiative. Nevertheless, I recognize that the decision by NIH made in conjunction with higher-level officials of the Department of Health and Human Services (DHHS) has a strong supporting rationale.

As I understand the issue, the crux of the problem is that the streamlined FDP procedure for noncompeting renewals has failed to win strong support among the NIH funding units. Colleagues at NIH report widespread concern among program- and grants-management staff because the noncompeting renewal procedure now being tested does not generate all the information they believe they need to fulfill their stewardship responsibilities. This conclusion in turn has reinforced misgivings that senior DHHS policy officials have held since this particular trial first was proposed. Whereas many hoped that real-world experience with the streamlined procedure might allay the early concerns, the opposite has proved true.

Under the circumstances, with so many key staff at several different levels of DHHS disinclined to endorse the streamlined renewal process, I see no chance that the Department will adopt it as standard policy. Further pursuit of this particular FDP activity as currently designed therefore is likely to be an unproductive expenditure of energy, resources, time, and good will. Regrouping and reassessing the issue in the light of the concerns generated by the trial seems the better course.

I view this setback as unfortunate but far from lethal for FDP. The NIH decision neither tarnishes the other FDP achievements nor diminishes the importance of our fundamental goals. Many still support FDP and that includes searching for a broadly acceptable way to address anew how we might make the noncompeting renewal process more efficient for both parties without an actual or perceived compromise of stewardship.

All best regards,

A handwritten signature in dark ink, appearing to read "D.A. Henderson", with a long horizontal stroke extending to the right.

D.A. Henderson, M.D., M.P.H.
Associate Director for Life Sciences

James Bartles, Ph.D.
Assistant Professor
Department of Cell, Molecular,
and Structural Biology
Northwestern University
Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008

Northwestern University Medical School

Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 9, 1992

Mr. William F. Raub
Special Assistant to the President for
Science and Technology
Old Executive Office Building
17th St. and Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Raub:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with the President's January 28, 1992 Memorandum for Certain Department Agency Heads on the subject of "Reducing the Burden of Government Regulations".

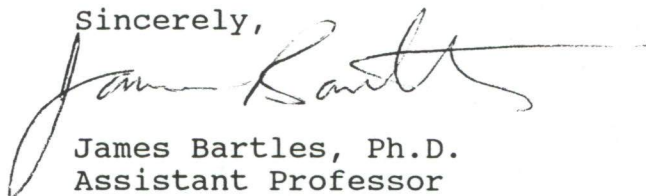
As you may know, the FDP was initiated in 1988 to help eliminate unnecessary administrative burdens on sponsored research and thereby enhance the research productivity of the United States. The noncompeting continuation pilot of the Federal Demonstration Project, initiated July 15, 1990, allowed participating federal agencies to issue out year funding commitments based upon an annual progress report. Some of the participating agencies, due to legal requirements or major procedural disruption, continued the requirement for a cover page. Other documentation was required only if significant changes occurred in the size or scope of a project.

A recent survey of the 1,092 researchers impacted by the noncompeting application process perhaps best demonstrates its importance. Overall, 1092 researchers reported time savings of 2.26 days under the noncompeting continuation demonstration of the FDP. Collectively, researchers saved 2464 days, with 90 percent of those days reinvested to scholarly activities. To provide another perspective on these "time reinvestments", it can be said that the study documents a total of 8.5 person-

years of additional scholarly activities. Further applying these rates of return, it is possible to project that the overall additional investment in research activity made possible by FDP was roughly eighteen person years of research.

I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in cursive script, appearing to read "James Bartles", with a long horizontal flourish extending to the right.

James Bartles, Ph.D.
Assistant Professor

Northwestern University Medical School

3576



Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 9, 1992

D. Allen Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
Room 358
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Bromely:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with President's January 28, 1992 Memorandum for Certain Department Agency Heads on the subject of "Reducing the Burden of Government Regulations".

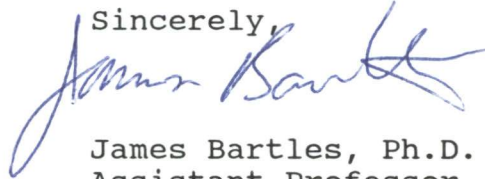
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years of additional scholarly activities. Further applying these rates of return, it is possible to project that the overall additional investment in research activity made possible by FDP was roughly eighteen person years of research.

I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in blue ink, appearing to read "James Bartles", with a stylized flourish at the end.

James Bartles, Ph.D.
Assistant Professor

TYPE: ACTION DOCUMENT NUMBER: 9203574
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: BERRY, Robert W.: NORTHWESTERN UNIVERSITY MEDICAL SCHOOL

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/09/92

SUBJECT: HE IS WRITING TO ASK FOR DR. BROMLEY'S ASSISTANCE IN
ENSURING THE CONTINUED PARTICIPATION OF NIH IN THE
FEDERAL DEMONSTRATION PROJECT.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: AS NECESSARY

SENDER'S DUE DATE:
OSTP DUE DATE: 12/28/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT: 12/17/92

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: An identical letter was sent to Bill Raub which was answered by
Dr. Henderson; therefore, the item has been handled for OSTP and
no additional action is needed. (donna- see attachment)

OSTP RECEIVED: 12/14/92 DEPT RECEIVED: 12/17/92
FILE: P-LIFE SCIENCES

CENTRAL FILES:



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

December 14, 1992

Dear Dr. Berry:

Thank you for your letter to Dr. William F. Raub regarding the decision by the National Institutes of Health (NIH) to discontinue its participation in one of the activities of the Federal Demonstration Project (FDP), i.e., the trial of a simplified application procedure for noncompeting continuation grants. Dr. Raub is no longer with the Office of Science and Technology Policy so I am replying to your inquiry. Your disappointment at this turn of events is understandable, for the procedures by which agencies of the federal government handle noncompeting renewal awards undoubtedly include unnecessary and unproductive administrative requirements and therefore are an appropriate focus for an FDP initiative. Nevertheless, I recognize that the decision by NIH made in conjunction with higher-level officials of the Department of Health and Human Services (DHHS) has a strong supporting rationale.

As I understand the issue, the crux of the problem is that the streamlined FDP procedure for noncompeting renewals has failed to win strong support among the NIH funding units. Colleagues at NIH report widespread concern among program- and grants-management staff because the noncompeting renewal procedure now being tested does not generate all the information they believe they need to fulfill their stewardship responsibilities. This conclusion in turn has reinforced misgivings that senior DHHS policy officials have held since this particular trial first was proposed. Whereas many hoped that real-world experience with the streamlined procedure might allay the early concerns, the opposite has proved true.

Under the circumstances, with so many key staff at several different levels of DHHS disinclined to endorse the streamlined renewal process, I see no chance that the Department will adopt it as standard policy. Further pursuit of this particular FDP activity as currently designed therefore is likely to be an unproductive expenditure of energy, resources, time, and good will. Regrouping and reassessing the issue in the light of the concerns generated by the trial seems the better course.

I view this setback as unfortunate but far from lethal for FDP. The NIH decision neither tarnishes the other FDP achievements nor diminishes the importance of our fundamental goals. Many still support FDP and that includes searching for a broadly acceptable way to address anew how we might make the noncompeting renewal process more efficient for both parties without an actual or perceived compromise of stewardship.

All best regards,

A handwritten signature in dark ink, appearing to read 'D.A. Henderson', with a stylized, flowing script.

D.A. Henderson, M.D., M.P.H.
Associate Director for Life Sciences

Robert W. Berry, Ph.D.
Professor
Department of Cell, Molecular,
and Structural Biology
Northwestern University
Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008

Northwestern University Medical School

Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 9, 1992

Mr. William F. Raub
Special Assistant to the President for
Science and Technology
Old Executive Office Building
17th St. and Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Raub:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with the President's January 28, 1992 Memorandum for Certain Department Agency Heads on the subject of "Reducing the Burden of Government Regulations".

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years of additional scholarly activities. Further applying these rates of return, it is possible to project that the overall additional investment in research activity made possible by FDP was roughly eighteen person years of research.

I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in cursive script, appearing to read "RW Berry".

Robert W. Berry, Ph.D.
Professor

Northwestern University Medical School

3574



Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 9, 1992

D. Allen Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
Room 358
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Bromely:

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Sincerely,

A handwritten signature in cursive script, appearing to read "R W Berry".

Robert W. Berry, Ph.D.
Professor

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203575
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: ANDERSON, Byron: NORTHWESTERN UNIVERSITY MEDICAL SCHOOL

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/09/92

SUBJECT: HE IS WRITING TO SEEK DR. BROMLEY'S ASSISTANCE IN
ENSURING THE CONTINUED PARTICIPATION OF NIH IN THE
FEDERAL DEMONSTRATION PROJECT.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: AS NECESSARY

SENDER'S DUE DATE:
OSTP DUE DATE: 12/28/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT: 12/17/92

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: An identical letter was sent to Bill Raub which was answered by
Dr. Henderson; therefore, the item has been handled for OSTP and
no additional action is needed. (donna - see attachment)

OSTP RECEIVED: 12/14/92 DEPT RECEIVED: 12/17/92
FILE: P-LIFE SCIENCES

CENTRAL FILES:



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

December 14, 1992

Dear Dr. Anderson:

Thank you for your letter to Dr. William F. Raub regarding the decision by the National Institutes of Health (NIH) to discontinue its participation in one of the activities of the Federal Demonstration Project (FDP), i.e., the trial of a simplified application procedure for noncompeting continuation grants. Dr. Raub is no longer with the Office of Science and Technology Policy so I am replying to your inquiry. Your disappointment at this turn of events is understandable, for the procedures by which agencies of the federal government handle noncompeting renewal awards undoubtedly include unnecessary and unproductive administrative requirements and therefore are an appropriate focus for an FDP initiative. Nevertheless, I recognize that the decision by NIH made in conjunction with higher-level officials of the Department of Health and Human Services (DHHS) has a strong supporting rationale.

As I understand the issue, the crux of the problem is that the streamlined FDP procedure for noncompeting renewals has failed to win strong support among the NIH funding units. Colleagues at NIH report widespread concern among program- and grants-management staff because the noncompeting renewal procedure now being tested does not generate all the information they believe they need to fulfill their stewardship responsibilities. This conclusion in turn has reinforced misgivings that senior DHHS policy officials have held since this particular trial first was proposed. Whereas many hoped that real-world experience with the streamlined procedure might allay the early concerns, the opposite has proved true.

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All best regards,

A handwritten signature in black ink, appearing to read "D.A. Henderson", with a stylized, cursive script.

D.A. Henderson, M.D., M.P.H.
Associate Director for Life Sciences

Byron Anderson, Ph.D.
Professor
Department of Cell, Molecular,
and Structural Biology
Northwestern University
Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008

Northwestern University Medical School

Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 9, 1992

Mr. William F. Raub
Special Assistant to the President for
Science and Technology
Old Executive Office Building
17th St. and Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Raub:

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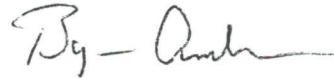
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I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in dark ink, appearing to read 'By - Anderson', with a long horizontal flourish extending to the right.

Byron Anderson, Ph.D.
Professor, CMS Biology

Northwestern University Medical School

3575



Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 9, 1992

D. Allen Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
Room 358
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Bromely:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with the President's January 28, 1992 Memorandum for Certain Department Agency Heads on the subject of "Reducing the Burden of Government Regulations".

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Sincerely,

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Byron Anderson, Ph.D.
Professor, CMS Biology

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203639
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: WINEGARD, W.C.: MINISTER FOR SCIENCE, CANADA

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/09/92

SUBJECT: HE IS FORWARDING NAMES FOR THE OTA STUDY ON THE
PATENTING OF GENE FRAGMENTS.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED: Clifford J. Gabriel

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: Necessary Action

SENDER'S DUE DATE:
OSTP DUE DATE: 01/04/93 STAFF DUE DATE 01/04/93
DATE COMPLETED: DATE COMPLETED/DEPT: 01/04/93

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 12/23/92
FILE: P-LIFE SCIENCES

DEPT RECEIVED: 12/28/92

CENTRAL FILES:



THE WHITE HOUSE
WASHINGTON

January 4, 1993

Bill
Dear Minister Winegard:

Thank you for submitting the names of Dr. Ronald Worton, Dr. Bartha Knoppers, and Mr. Graham Strachan as potential contacts from Canada for the OTA project on patenting human DNA sequences. I have forwarded this information to Dr. Robyn Nashimi, OTA Project Director for this activity.

Sincerely yours,

Allan
D. Allan Bromley
The Assistant to the President
for
Science and Technology

The Honorable William Charles Winegard
Minister for Science
Department of Industry, Science
and Technology, Canada
C.D. Howe Building
Ottawa
Ontario K1A 0H5

Minister for Science



Ministre des Sciences

3C29

December 9, 1992

Dr. D. Allan Bromley
The Assistant to the President
for Science and Technology
The White House
Washington, D.C.

Dear Dr. Bromley,

Thank you for your correspondence of October 28th, 1992 in which you asked me to suggest the names of one or two possible contributors from Canada to a proposed study on patenting gene fragments. I understand that this study will now be undertaken by the Congressional Office of Technology Assessment (OTA).

The names of the following possible Canadian contributors can be forwarded to OTA for consideration. All three have been advised of the upcoming OTA study, and have indicated their willingness to participate.

Dr. Ronald Worton
Geneticist-in-Chief
Department of Genetics
Hospital for Sick Children
555 University Avenue
Toronto, Ontario
M5G 1X8

Tel: (416) 813-6385
Fax: (416) 813-4931

Dr. Bartha Knoppers
Faculté de droit
Université de Montréal
3101 chemin de la Tour
C.P. 6128, succursale A
Montréal, Québec
H3C 3J7

Tel: (514) 343-6714
Fax: (514) 343-2199

.../2

Mr. Graham Strachan
President
Allelix Pharmaceuticals Inc.
6850 Goreway Drive
Mississauga, Ontario
L4V 1P1

Tel: (416) 677-0831
Fax: (416) 677-9595

I am pleased that the study will include a review of international intellectual property rights issues, and that the review goes beyond the biotechnology industry itself, and extends to the more general area of future scientific collaboration.

I look forward to seeing the results of this study when available.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "W.C. Winegard", is written in a cursive style.

W.C. Winegard

"Document Control for Division of Life Sciences"

TYPE: ACTION DOCUMENT NUMBER: 9203581
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

FROM: ADAM, Stephen: NORTHWESTERN UNIVERSITY MEDICAL SCHOOL

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/07/92

SUBJECT: HE IS WRITING TO SEEK DR. BROMLEY'S ASSISTANCE IN
ENSURING THE CONTINUED PARTICIPATION OF NIH IN THE
FEDERAL DEMONSTRATION PROJECT.

DIRECTORATE STAFF
ASSIGNED: LIFE SCIENCES ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION: AS NECESSARY

SENDER'S DUE DATE:
OSTP DUE DATE: 12/28/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT: 12/17/92

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS: An identical letter was sent to Bill Raub which was answered by
Dr. Henderson; therefore, the item has been handled for OSTP and
no additional action is needed. (donna - see attachment)

OSTP RECEIVED: 12/14/92
FILE: P-LIFE SCIENCES

DEPT RECEIVED: 12/17/92

CENTRAL FILES:



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

December 11, 1992

Dear Dr. Adam:

Thank you for your letter to Dr. William F. Raub regarding the decision by the National Institutes of Health (NIH) to discontinue its participation in one of the activities of the Federal Demonstration Project (FDP), i.e., the trial of a simplified application procedure for noncompeting continuation grants. Dr. Raub is no longer with the Office of Science and Technology Policy so I am replying to your inquiry. Your disappointment at this turn of events is understandable, for the procedures by which agencies of the federal government handle noncompeting renewal awards undoubtedly include unnecessary and unproductive administrative requirements and therefore are an appropriate focus for an FDP initiative. Nevertheless, I recognize that the decision by NIH made in conjunction with higher-level officials of the Department of Health and Human Services (DHHS) has a strong supporting rationale.

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All best regards,



D.A. Henderson, M.D., M.P.H.
Associate Director for Life Sciences

Stephen Adam, Ph.D.
Assistant Professor
Department of Cell, Molecular,
and Structural Biology
Northwestern University
Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008

Northwestern University Medical School

Department of Cell, Molecular
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912-4516

December 7, 1992

Mr. William F. Raub
Special Assistant to the President for
Science and Technology
Old Executive Office Building
17th St. and Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Raub:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with the President's January 28, 1992 Memorandum for Certain Department and Agency Heads on the subject of "Reducing the Burden of Government Regulations".

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Page 2

I appreciate your efforts in ensuring the continuation of this project of demonstrated importance to the academic community and the nation's research enterprise.

Sincerely,

A handwritten signature in cursive script that reads "Stephen Adam".

Stephen Adam, Ph.D.
Assistant Professor

RC:cb

Northwestern University Medical School

3581



Department of Cell, Molecular,
and Structural Biology

Ward Building
303 East Chicago Avenue
Chicago, Illinois 60611-3008
(312) 503-8250
Fax (312) 503-7912/4516

December 7, 1992

D. Allen Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
Room 358
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. Bromely:

I write to solicit your assistance in ensuring the continued participation of the National Institutes of Health in the noncompeting continuation demonstration of the Federal Demonstration Project (FDP). The continuation of this demonstration, with full participation of the National Institutes of Health, is consistent with the President's January 28, 1992 Memorandum for Certain Department and Agency Heads on the subject of "Reducing the Burden of Government Regulations".

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Page 2

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Sincerely,

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Stephen Adam, Ph.D.
Assistant Professor

RC:cb