

Contact Person: Marcia Litwack, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7804, Bethesda, MD 20892, (301) 435-1719.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393-396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-31210 Filed 12-6-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Methods and Compositions for the Detection and Treatment of Insulin Dependent Diabetes

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: US Patent Application Serial Number 08/548,159 filed 10/95 by McClaren, Notkins, Lan, and Li, and foreign counterparts, and US Patent Application Serial Number 08/514,213 filed 8/95, and foreign counterparts, by McClaren, Notkins, and Lan—both entitled “Methods and Compositions for the Detection and Treatment of Insulin Dependent Diabetes” to BioSeek Inc., of New York, NY. The United States of America is an assignee of the patent rights to these inventions.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before February 5, 2001 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: John Rambossek, Ph.D. Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Su9ite 325, Rockville, MD 20852-3804; Email: jr312d@nih.gov; Telephone: (301) 496-7056, ext. 270; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: Insulin-dependent diabetes mellitus (IDDM) affects close to one million people in the United States. It is autoimmune disease in which the immune system produces antibodies that attack the body's own insulin-manufacturing cells in the pancreas. Patients require daily injections of insulin to regulate blood sugar levels. The invention identifies two proteins, named IA-2 and IA-2 β , that are important markers for type I (juvenile, insulin-dependent) diabetes. IA-2/IA-2 β , when used in diagnostic tests, recognized autoantibodies in 70 percent of IDDM patients. Combining IA-2 and IA-2 β with other known markers increased the level of identification to 90 percent of individuals with IDDM. Moreover, the presence of autoantibodies to IA-2 and IA-2 β in otherwise normal individuals was highly predictive in identifying those at risk of ultimately developing clinical disease. It is now possible to develop a rapid and effective test that can screen large populations for IDDM. In addition, IA-2 and IA-2 β are candidates for immune tolerance and prevention of disease development. The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective license may be limited to use of the invention for diagnostic and therapeutic uses in the detection and treatment of diabetes. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 30, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 00-31215 Filed 12-6-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Compositions and Methods for the Stimulation of Proliferation and Differentiation of Pancreatic Cells Ex Vivo

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in any U.S. patents 5,888,705 (03/30/1999) and 5,587,309 (12/24/1996) or foreign applications corresponding to PCT Patent Application PCT/US95/00521, entitled “Compositions and Method of Stimulating the Proliferation and Differentiation of Human Fetal and Adult Pancreatic Cells Ex Vivo” published as WO 95/29989 (11/09/1995) to PanCel Corp., of California. The prospective exclusive license may be limited to the development of therapeutic applications, including compositions and methods using adult pancreatic cells, to be used in the treatment of diabetes.

DATES: Only written comments and/or applications for a license which are received by NIH on or before February 5, 2001, will be considered.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comment and other materials relating to the contemplated license should be directed to Susan S. Rucker, J.D., Patent and Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext 245; fax: 301/402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The patents and patent applications describe the use of the compound Hepatocyte Growth Factor/Scatter Factor (HGF/SF) for the stimulation of proliferation and differentiation of pancreatic cells. Upon exposure to HGF/SF the pancreatic cells proliferate and differentiate and are able to produce insulin. The ability to stimulate pancreatic cells to proliferate and differentiate into cells capable of producing insulin may provide a means

for improving the treatment of Type I and Type II diabetes.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. This prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license (*i.e.*, a completed "Application for License to Public Health Service Inventions") in the indicated exclusive field of use filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act 35 U.S.C. 552.

Dated: November 29, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.
[FR Doc. 00-31217 Filed 12-6-00; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Warren Grant Magnuson Clinical Center; Proposed Collection; Comment Request; Customer and Other Partners Satisfaction Surveys

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Warren Grant Magnuson Clinical Center (CC), the National Institutes of Health, (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Generic Clearance for Satisfaction Surveys of Customer and Other Partners.

Type of Information Collection Request: Extension (OMB control number: 0925-0458).

Need and Use of Information Collection: The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the satisfaction of various Clinical Center customers and other partners with Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; and (4) to evaluate the satisfaction of various Clinical Center customers and other partners with implemented service modifications. These surveys will almost certainly lead

to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization.

Frequency of Response: The participants will respond yearly.

Affected public: Individuals and households; businesses and other for profit, small businesses and organizations.

Types of respondents: These surveys are designed to assess the satisfaction of the Clinical Center's major internal and external customers with the services provided. These customers include, but are not limited to, the following groups of individuals: Clinical Center patients, family members of Clinical Center patients, visitors to the Clinical Center, National Institutes of Health investigators, NIH intramural collaborators, private physicians or organizations who refer patients to the Clinical center, volunteers, vendors and collaborating commercial enterprises, small businesses, regulators, and other organizations. The annual reporting burden is as follows:

TABLE 1.—THREE YEAR BURDEN ESTIMATE

Customer	Type of survey	Estimated number to be surveyed	Expected response rate (percent)	Time to complete survey (minutes)	Estimated burden hours
Clinical Center Patients	Questionnaire	11,100	66	20	2436.6
	Telephone				
Family Members of Patients	Questionnaire/	8500	38	10	533.3
	Post Card				
Visitors to the Clinical Center	Questionnaire/	3500	15	10	87.5
	Post Card				
Former physician employees and trainees	Electronic	650	35	10	38.2
Guest workers/Guest researchers	Electronic	950	60	22	210
Extramural collaborators	Electronic	600	30	15	45
Vendors and Collaborating Commercial Enterprises	Questionnaire/	9500	17	18	475
	Fax Back				
Professionals and Organizations Referring Patients	Fax Back	9000	30	28	1250
Regulators	Fax Back	85	82	19	22
Volunteers	Questionnaire	850	58	28	230
Total (3 Years)	n=16,812	5,327.6
Total (1 Year)	n=5,604	1,776.0