Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21122 Filed 10–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; the Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 21, 2007, pages 46640–46641, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. *Type of Information Collection Request:* Renewal (OMB No. 0925–0493). *Need and Use of Information Collection:* This project identifies and quantifies factors associated with the presence and progression of subclinical cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE–99–11–08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 550; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* .2; and *Estimated Total Annual Burden Hours Requested:* 36.7. The annualized cost to respondents is estimated at $5,595, assuming respondents time at the rate of $18.65 per hour and physician time at the rate of $75 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondent	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Physicians	250	1	0.20	16.7
Proxies	300	1	0.20	20
Total	550	1	0.20	36.7

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Jean Olson, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD, 20892–7936, or call 301–435–0397 (non-toll-free number), or e-mail your request, including your address to: *OlsonJ@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: October 16, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: October 18, 2007.

Suzanne Freeman,

OMB Clearance Officer, NHLBI, National Institutes of Health.

[FR Doc. E7–21103 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Cell-Nanofiber Composite Based Engineered Cartilage

Description of Invention: Available for licensing and commercial development is a tissue-engineered cartilage derived from a cellular composite made from a biodegradable, biocompatible polymeric nanofibrous matrix having dispersed chondrocytes or adult mesenchymal stem cells. More particularly, tissue-engineered cartilage can be prepared where the cartilage has a biodegradable and biocompatible nanofibrous polymer matrix prepared by electrospinning and a plurality of chondocytes or mesenchymal stem cells dispersed in the pores of the matrix. The tissue-engineered cartilage possesses compressive strength properties similar to natural cartilage.

The electrospinning process is a simple, economical means to produce biomaterial matrices or scaffolds of ultra-fine fibers derived from a variety of biodegradable polymers (Li WJ, *et al. J. Biomed. Mater. Res.* 2002; 60:613–21). Nanofibrous scaffolds (NFSs) formed by electrospinning, by virtue of structural similarity to natural extracellular matrix (ECM), may represent promising structures for tissue engineering applications. Electrospun three-dimensional NFSs are characterized by high porosity with a wide distribution of pore diameter, high-surface area to volume ratio and morphological similarities to natural collagen fibrils (Li WJ, *et al. J. Biomed. Mater. Res.* 2002; 60:613–21). These physical characteristics promote favorable biological responses of seeded cells in vitro and in vivo, including enhanced cell attachment, proliferation, maintenance of the chondrocytic phenotype (Li WJ, *et al. J. Biomed. Mater. Res.* 2003; 67A: 1105–14), and support of chondrogenic differentiation (Li WJ, *et al. Biomaterials* 2005; 26:599–609) as well as other connective tissue linage differentiation (Li WJ, *et al. Biomaterials* 2005; 26:5158–5166). The invention based on cell-nanofiber composite represents a candidate engineered tissue for cell-based approaches to cartilage repair.

Application: Cartilage repair and methods for making tissue-engineered cartilage.

Developmental Status: Electrospinning method is fully developed and cartilage has been synthesized.

Inventors: Wan-Ju Li and Rocky Tuan (NIAMS).

Publications: The invention is further described in:

1. W–J Li *et al.* Engineering controllable anisotropy in electrospun biodegradable nanofibrous scaffolds for musculoskeletal tissue engineering. J Biomech. 2007;40(8):1686–1693. Epub 2006 Oct 23, doi:10.1016/jbiomech.2006.09.004.

2. W–J Li *et al.* Fabrication and characterization of six electrospun poly(alpha-hydroxy ester)-based fibrous scaffolds for tissue engineering applications. Acta Biomater. 2006 Jul;2(4):377–385. Epub 2006 May 6, doi:10.1016/j.actbio.2006.02.005.

3. CK Kuo *et al.* Cartilage tissue engineering: its potential and uses. Curr Opin Rheumatol. 2006 Jan;18(1):64–73. Review.

4. W–J Li *et al.* Multilineage differentiation of human mesenchymal stem cells in a three-dimensional nanofibrous scaffold. Biomaterials. 2005 Sep;26(25):5158–5166.

Patent Status:

U.S. Provisional Application No. 60/690,998 filed 15 Jun 2005 (HHS Reference No. E–116–2005/0–US–01).

PCT Application No. PCT/US2006/0237477 filed 15 Jun 2006 (HHS Reference No. E–116–2005/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukasp@mail.nih.gov.

Cell-Nanofiber Composite and Cell-Nanofiber Composite Amalgam Based Engineered Intervertebral Disc

Description of Invention: Diseased or damaged musculoskeletal tissues are often replaced by an artificial material, cadaver tissue or donated, allogenic tissue. Tissue engineering offers an attractive alternative whereby a live, natural tissue is generated from a construct made up of a patient's own cells or an acceptable/compatible cell source in combination with a biodegradable scaffold for replacement of defective tissue.

Degeneration of the intervertebral disc (IVD) is a common and significant source of morbidity in our society. Approximately 8 of 10 adults at some point in their life will experience an episode of significant low back pain, with the majority improving without any formal treatment. However, for the subject requiring surgical management current interventions focus on fusion of the involved IVD levels, which eliminates pain but does not attempt to restore disc function. Approximately 200,000 spinal fusions were performed in the United States in 2002 to treat pain associated with lumbar disc degeneration. Spinal fusion however is thought to significantly alter the biomechanics of the disc and lead to further degeneration, or adjacent segment disease. Therefore, in the past decade there has been mounting interest in the concept of IVD replacement. The replacement of the IVD holds tremendous potential as an alternative to spinal fusion for the treatment of degenerative disc disease by offering a safer alternative to current spinal fusion practices.

At the present time, several disc replacement implants are at different stages of preclinical and clinical testing. These disc replacement technologies are designed to address flexion, extension, and lateral bending motions; however, they do little to address compressive forces and their longevity is limited due to their inability to biointegrate. Therefore, a cell-based tissue engineering approach offers the most promising alternative to replace the degenerated IVD. Current treatment for injuries that penetrate subchondral bone include subchondral drilling, periosteal tissue grafting, osteochondral allografting, chondrogenic cell and transplantation; but are limited due to suboptimal integration with host tissues.

The present invention claims tissue engineered intervertebral discs comprising a nanofibrous polymer hydrogel amalgam having cells dispersed therein, methods of fabricating tissue engineered intervertebral discs by culturing a mixture of stem cells or intervertebral disc cells and a electrospun nanofibrous polymer hydrogel amalgam in a suitable bioreactor, and methods of treatment comprising implantation of tissue engineered intervertebral disc into a subject.

Application: Intervertebral disc bio-constructs and electrospinning methods for fabrication of the discs.

Developmental Status: Prototype devices have been fabricated and preclinical studies have been performed.

Inventors: Wan-Ju Li, Leon Nesti, Rocky Tuan (NIAMS).

Patent Status:

U.S. Provisional Application No. 60/847,839 filed 27 Sep 2006 (HHS Reference No. E–309–2006/0–US–01).

U.S. Provisional Application No. 60/848,284 filed 28 Sep 2006 (HHS Reference No. E–309–2006/1–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Bioreactor Device and Method and System for Fabricating Tissue

Description of Technology: Available for licensing and commercial development is a millifluidic bioreactor system for culturing, testing, and fabricating natural or engineered cells and tissues. The system consists of a millifluidic bioreactor device and methods for sample culture. Biologic samples that can be utilized include cells, scaffolds, tissue explants, and organoids. The system is microchip controlled and can be operated in closed-loop, providing controlled delivery of medium and biofactors in a sterile temperature regulated environment under tabletop or incubator use. Sample perfusion can be applied periodically or continuously, in a bidirectional or unidirectional manner, and medium re-circulated.

Advantages:

The device is small in size, and of conventional culture plate format.

Provides the ability to grow larger biologic samples than microfluidic systems, while utilizing smaller medium volumes than conventional bioreactors. The bioreactor culture chamber is adapted to contain sample volumes on a milliliter scale (10 [mu]L to 1 mL, with a preferred size of 100 [mu]L), significantly larger than chamber volumes in microfluidic systems (on the order of 1 [mu]L). Typical microfluidic systems are designed to culture cells and not larger tissue samples.

The integrated medium reservoirs and bioreactor chamber design provide for, (1) concentration of biofactors produced by the biologic sample, and (2) the use of smaller amounts of exogenous biofactor supplements in the culture medium. The local medium volume (within the vicinity of the sample) is less than twice the sample volume. The total medium volume utilized is small, preferably 2 ml, significantly smaller than conventional bioreactors (typically using 500–1000 mL).

Provides for real-time monitoring of sample growth and function in response to stimuli via an optical port and embedded sensors. The optical port provides for microscopy and spectroscopy measurements using transmitted, reflected, or emitted (e.g., fluorescent, chemiluminescent) light. The embedded sensors provide for measurement of culture fluid pressure and sample pH, oxygen tension, and temperature.

Capable of providing external stimulation to the biologic sample, including mechanical forces (e.g. fluid shear, hydrostatic pressure, matrix compression, microgravity via clinorotation), electrical fields (e.g., AC currents), and biofactors (e.g., growth factors, cytokines) while monitoring their effect in real-time via the embedded sensors, optical port, and medium sampling port.

Monitoring of biologic sample response to external stimulation can be performed non-invasively and non-destructively through the embedded sensors, optical port, and medium sampling port. Testing of tissue mechanical and electrical properties (e.g., stiffness, permeability, loss modulus via stress or creep test, electrical impedance) can be performed over time without removing the sample from the bioreactor device.

The bioreactor sample chamber can be constructed with multiple levels fed via separate perfusion circuits, facilitating the growth and production of multiphasic tissues.

Application: Cartilage repair and methods for making tissue-engineered cartilage.

Development Stage: Electrospinning method is fully developed and cartilage has been synthesized.

Inventors: Juan M. Taboas (NIAMS), Rocky S. Tuan (NIAMS), et al.

Patent Status:

U.S. Provisional Application No. 60/701,186 filed 20 Jul 2005 (HHS Reference No. E–042–2005/0–US–01).

PCT Application No. PCT/US2006/028417 filed 20 Jul 2006, which published as WO 2007/012071 on 25 Jan 2007 (HHS Reference No. E–042–2005/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Dated: October 22, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–21100 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Teleconference Regarding Licensing and Collaborative Research Opportunities for: Treatment of Autoimmune and Allergic Disorders (NIAID)

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

ACTION: Notice.

Technology Summary

These technologies relate to compositions and methods useful in treating autoimmune diseases generally, and Multiple Sclerosis specifically.

Technology Description

Scientists at the NIH have discovered a method for the treatment or prevention of autoimmune diseases, allergic or atopic disorders, and graft rejections. This method selectively induces apoptosis of disease causing T lymphocytes, while sparing the majority of T-cells. Cell death is achieved by the cyclical administration of disease specific antigens and IL–2.

Further, the NIH scientists have developed compositions and methods for clinical assessment, diagnosis and treatment of Multiple Sclerosis (MS). The compositions are molecules related to the human proteolipid protein (PLP), and the 21.5 kDA fetal isoform of human myelin basic protein (MBP), including nucleic acids and polypeptides. The polypeptides can be used to assay T-cells for responsiveness to MBP and PLP epitopes. They are further useful as therapeutic agents for treating MS by inducing T-cell apoptosis. The inventors have demonstrated that treatment with MP4, a protein chimera of MBP, and a modified form of PLP, termed PLP4, prevented clinical symptoms of MS in both rodent and non-human primates. They have also completed primate toxicity tests demonstrating the compounds are non-toxic.

Novel application of these methods described in these technologies include:

Infusion of autoimmune disease antigen peptides reduces the severity of allergic diseases.