B. Regular Review of Compliance Program Effectiveness

Nursing facilities should regularly review the implementation and execution of their compliance program systems and structures. This review should be conducted periodically, typically on annual basis. The assessment should include an evaluation of the overall success of the program, as well as each of the basic elements of a compliance program individually, which include:

- Designation of a compliance officer and compliance committee;
- Development of compliance policies and procedures, including standards of conduct;
- Developing open lines of communication;
- Appropriate training and teaching;
- Internal monitoring and auditing;
- Response to detected deficiencies; and
- Enforcement of disciplinary standards.

Nursing facilities seeking guidance for establishing and evaluating their compliance operations should review OIG's 2000 Nursing Facility CPG, which explains in detail the fundamental elements of a compliance program.[133] Nursing facilities may also wish to consult quality of care corporate integrity agreements (CIA) entered into between OIG and parties settling specific matters.[134] Other issues a nursing facility may want to evaluate are whether there has been an allocation of adequate resources to compliance initiatives; whether there is a reasonable timetable for implementation of the compliance measures; whether the compliance officer and compliance committee have been vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures; and whether compensation structures create undue pressure to pursue profit over compliance.

V. Self-Reporting

If the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the nursing facility should promptly report the existence of the misconduct to the appropriate Federal and State authorities.[135] The reporting should occur within a reasonable period, but not longer than 60 days,[136] after determining that there is credible evidence of a violation.[137] Prompt voluntary reporting will demonstrate the nursing facility's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, prompt reporting of misconduct will be considered a mitigating factor by OIG in determining administrative sanctions (*e.g.*, penalties, assessments, and exclusion) if the reporting nursing facility becomes the subject of an OIG investigation.[138]

To encourage providers to make voluntary disclosures to OIG, OIG published the Provider Self-Disclosure Protocol.[139] When reporting to the Government, a nursing facility should provide all relevant information regarding the alleged violation of applicable Federal or State law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from governmental authorities, may be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation. This notification should include a description of the impact of the alleged violation on the applicable Federal health care programs or their beneficiaries.

VI. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for health care, it is imperative for nursing facilities to establish and maintain effective compliance programs. These programs should foster a culture of compliance and a commitment to delivery of quality health care that begins at the highest levels and extends throughout the organization. This supplemental CPG is intended as a resource for nursing facilities to help them operate effective compliance programs that decrease errors, fraud, and abuse and increase quality of care and compliance with Federal health care program requirements for the benefit of the nursing facilities and their residents.

Dated: September 24, 2008.

Daniel R. Levinson,

Inspector General.

[FR Doc. E8–22796 Filed 9–29–08; 8:45 am]

BILLING CODE 4152–01–P

[133] 2000 Nursing Facility CPG, *supra* note 2, at 14289.

[134] OIG, ''HHS—OIG—Fraud Prevention & Detection—Corporate Integrity Agreements,'' available on our Web site at *http://oig.hhs.gov/fraud/cias.html.*

[135] Appropriate Federal and State authorities include OIG, CMS, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Department's Office for Civil Rights, the Federal Trade Commission, the Drug Enforcement Administration, the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as the State Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, the Health Resources and Services Administration, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

[136] To qualify for the ''not less than double damages'' provision of the False Claims Act, the provider must provide the report to the Government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

[137] Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, OIG believes a provider should immediately report misconduct that: (i) Is a clear violation of administrative, civil, or criminal laws; (ii) poses an imminent danger to a patient's safety; (iii) has a significant adverse effect on the quality of care provided to Federal health care program beneficiaries; or (iv) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

[138] OIG has published criteria setting forth those factors that OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997), ''Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act.''

[139] For details regarding the Provider Self-Disclosure Protocol, including timeframes and required information, see 63 FR 58399 (October 30, 1998), ''Publication of the OIG's Provider Self-Disclosure Protocol,'' available on our Web site at *http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf. See also* OIG's April 15, 2008, Open Letter to Health Care Providers, available on our Web site at *http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4–15–08.pdf;* OIG's April 24, 2006, Open Letter to Health Care Providers, available on our Web site at *http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf.*

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.

Transgenic Mice With Conditionally-Enhanced Bone Morphogen Protein (BMP) Signaling: A Model for Human Bone Diseases

Description of Technology: This technology relates to novel animal models of several human bone diseases that have been linked to enhanced BMP signaling. More specifically, this mouse model expresses a mutant receptor for BMP, known as Alk2 that is always actively signaling. This receptor is under the control of the Cre-loxP system, which allows control of expression of the mutant Alk2 in both a developmental and tissue-specific manner. As a result, the enhanced signaling conditions exhibited in multiple human bone-related diseases can be studied with the same animals.

Applications: The mouse model can be applied to the study of BMP signaling-related human diseases such as fibrodysplasia ossificans progressiva, which involves the postnatal transformation of connective tissue into bone. Another example of BMP signaling-related disease is Craniosynostosis, which involves the premature closing of the sutures in childhood so that normal brain and skull growth are inhibited. This mouse model can potentially be used in other human diseases where BMP signaling might play a pivotal role, for example cleft lip and cleft palate, breast cancer, osteoarthritis, lung fibrosis, multiple myeloma, juvenile polyposis, cephalic neural tube closure defects, diabetes and other types of blood glucose control problems, and pulmonary hypertension.

Development Status: Early-stage development.

Inventors: Yuji Mishina, Manas Ray, Greg Scott (NIEHS).

Relevant Publications:

1. T Fukada *et al.* Generation of a mouse with conditionally activated signaling through the BMP receptor, ALK2. Genesis. 2006;44:159–167.
2. L Kan *et al.* Transgenic mice overexpressing BMP4 develop a fibrodysplasia ossificans progressiva (FOP)-like phenotype. Am J Path. 2004 Oct;165(4):1107–1115.
3. EM Shore *et al.* A recurrent mutation in the BMP type I receptor ACVR1 causes inherited and sporadic fibrodysplasia ossificans progressive. Nat Genet. 2006 May;38(5):525–527.

Patent Status: HHS Reference No. E–328–2008/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@mail.nih.gov*.

Production of Endotoxin Free TEV Protease

Description of Technology: This technology relates to an efficient method of purifying proteins. More specifically, this technology relates to a method of obtaining an endotoxin-free 'TEV protease,' a common name for a 27 kDa catalytic domain of the Nuclear Inclusion a (NIa) protein from Tobacco Etch Virus. TEV protease is a site-specific protease that can be used to cleave purified fusion proteins that have been engineered to contain a TEV protease cleavage site. This is typically done to enable stable expression and purification of a protein of interest. The technology consists of (a) the DNA construct (created by Dom Esposito) to allow expression of the protein in insect cells, (b) the insect cell line, and (c) the purification protocol. TEV protease itself is expressed as a fusion to MBP (Maltose Binding Protein) to enhance solubility.

Advantages: TEV protease expressed and produced in *E. coli* contains substantial amounts of endotoxin, which presents a barrier to use where the final purified product is required to be endotoxin-free. It is important to note that all proteins which are used for therapeutic purposes must have little or no endotoxin for safety reasons. The method of obtaining an endotoxin-free TEV protease is to express and purify TEV protease using a baculovirus/insect cell expression system, instead of *E. coli* which results in an endotoxin-free TEV protease.

Development Status: Early stage development.

Inventors: William K. Gillette, Dominic Esposito, and Ralph Hopkins (SAIC/NCI).

Relevant Publication: RB Kapust and DS Waugh. Controlled intracellular processing of fusion proteins by TEV protease. Protein Expr Purif. 2000 Jul;19(2):312–318.

Patent Status: HHS Reference No. E–139–2008/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Steve Standley, PhD; 301–435–4074; *sstand@mail.nih.gov*.

Association of the ECHDCI/RNF146 Gene Region on Human Chromosome 6q With Breast Cancer Risk and Protection

Description of Technology: The technology describes a genetic locus (ECHDC l/RNF146 gene region on human chromosome 6q) that may be predictive for risk of breast cancer in relatives of individuals diagnosed with breast cancer. Furthermore, the invention provides evidence that one or more polymorphism alleles in chromosome 6q22.33 indicates a lower risk or increased risk of developing breast cancer in individuals.

Applications:

- The invention has the potential of being developed into a predictive diagnostic test, for people at a risk of breast cancer, together with other risk factors for the disease, such as age, parity, and other genetic contributions especially for predicting risk of breast cancer in individuals free of BRCA1 and BRCA2 polymorphism.
- The invention may help to develop pharmaceuticals through elucidation of the contributing biochemical, etiologic pathway.

Advantages: This study was a clinical study in a cohort of individuals. Thus the relevance of the data is of considerable significance.

Development Status: Validation of the correlation between the polymorphisms and risk of breast cancer is ongoing using different cohorts.

Inventors: Bert Gold *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/023,936 filed 28 Jan 2008 (HHS Ref. No. E–065–2008/0–US–01).

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov*.

Novel Chemoattractant-Based Toxins to Improve Vaccine Immune Responses for Cancer and Infectious Diseases

Description of Technology: Cancer is one of the leading causes of death in the United States and it is estimated that there will be more than half a million

deaths caused by cancer in 2008. A major drawback of the current chemotherapy-based therapeutics is the cytotoxic side-effects associated with them. Thus there is a dire need to develop new therapeutic strategies with fewer side-effects. Immuno-therapy has taken a lead among the new therapeutic approaches. Enhancing the innate immune response of an individual has been a key approach for the treatment against different diseases such as cancer and infectious diseases.

This technology involves the generation of novel chemoattractant toxins that deplete the T regulatory cells (Treg) or other immunosuppressive or hyperactivated cells locally. Treg controls activation of immune responses by suppressing the induction of adaptive immune responses, particularly T cell responses. Immunosuppressive cells such as tumor infiltrating macrophages or NKT and other cells down regulate antitumor immune responses. The chemoattractant toxins consist of a toxin moiety fused with a chemokine receptor ligand, chemokines and other chemoattractants that enables specific targeting and delivery to the Treg cells. This technology is advantageous over the more harmful antibodies and chemicals that are currently used for the systemic depletion of Treg cells. The current technology can be used therapeutically in a variety of ways. They can be used together with vaccines to increase efficacy of the vaccine for the treatment of cancer, and can be used to locally deplete Treg cells or other immuno suppressive cells to induce cytolytic cell responses at the tumor site or to eliminate chronic infectious diseases such as HIV and tuberculosis.

Applications:

- New chemoattractant based toxins targeted towards Treg cells.
- New chemoattractant based toxins targeted towards immunosuppressive NKT, and macrophages.
- New chemoattractant based toxins targeted towards local depletion of hyperactivated CD4 T cells to treat autoimmune diseases.
- Chemoattractant based toxins depleting Treg cells or other immunosuppressive cells causing enhanced vaccine immune responses.
- Novel immunotherapy by increasing vaccine efficacy against cancer and infectious diseases.

Market:

- 565,650 deaths from cancer related diseases estimated in 2008.
- The technology platform involving novel chemo-attractant based toxins can be used to improve vaccine immune responses. The cancer vaccine market is expected to increase from $135 million in 2007 to more than $8 billion in 2012.
- The technology platform has additional market in treating several other clinical problems such as autoimmune diseases.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Arya Biragyn (NIA), Dolgor Bataar (NIA), *et al.*

Related Publications:

1. Copy of manuscript from this technology can be provided once accepted for publication.

2. M Coscia, A Biragyn. Cancer immunotherapy with chemoattractant peptides. Semin Cancer Biol 2004 Jun;14(3):209–218.

3. R Schiavo *et al.* Chemokine receptor targeting efficiently directs antigens to MHC class I pathways and elicits antigen-specific CD8+ T-cell responses. Blood 2006 Jun 15;107 (12):4597–4605.

Patent Status: U.S. Patent Application filed 28 Mar 2008, claiming priority to 30 Sep 2005 (HHS Reference No. E–027–2005/0–US–06).

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

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The NIA Laboratory of Immunology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize novel chemoattractant-based toxins. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: September 18, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–22889 Filed 9–29–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Review of Education and Career Development Award Applications.

Date: October 24, 2008.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Sand Key Resort, 1160 Gulf Boulevard, Clearwater, FL 33767.

Contact Person: Robert Bird, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8113, Bethesda, MD 20892–8328, 301–496–7978, *birdr@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Prevention Research Small Grant Program (R03).

Date: October 30–31, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, Marriot, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Irina Gordienko, PhD, Scientific Review Officer, Scientific Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 7073, Bethesda, MD 20892, 301–594–1566, *gordienkoiv@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Community Clinical Oncology Program (CCOP).

Date: November 5, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892–8329, 301–496–7987, *lovingeg@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)