family interacting protein 3 (FIP3) expressed in the pGEX2T vector.

Application: Research tool to detect and quantify activated Arf5 in various laboratory procedures to analyze intracellular trafficking and cellular motility.

Advantages: To the best of our knowledge, this technology represents the first reported assay for the detection of activated Arf5.

Inventors: Paul A. Randazzo and Vi L. Ha (NCI).

Publications:

1. H Inoue *et al.* Arf GTPase-activating protein ASAP1 interacts with Rab11 effector FIP3 and regulates pericentrosomal localization of transferrin receptor-positive recycling endosome. Mol Biol Cell. 2008 Oct;19(10):4224–4237.

2. HY Yoon *et al.* In vitro assays of Arf1 interaction with GGA proteins. Methods Enzymol. 2005;404:316–332.

Patent Status: HHS Reference No. E–064–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technologies: Antibodies and Antisera Recognizing Members of the ArfGap Family of Proteins:

- HHS Reference No. E–220–2008/0—Research Tool.
- HHS Reference No. E–220–2008/1—Research Tool.
- HHS Reference No. E–220–2008/2—Research Tool.
- HHS Reference No. E–221–2008/0—Research Tool.
- HHS Reference No. E–221–2008/1—Research Tool.
- HHS Reference No. E–221–2008/2—Research Tool.
- HHS Reference No. E–222–2008/0—Research Tool.
- HHS Reference No. E–242–2008/0—Research Tool.
- HHS Reference No. E–243–2008/0—Research Tool.
- HHS Reference No. E–244–2008/0—Research Tool.
- HHS Reference No. E–245–2008/0—Research Tool.
- HHS Reference No. E–245–2008/1—Research Tool.
- HHS Reference No. E–252–2008/0—Research Tool.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Samuel E. Bish, PhD; 301–435–5282; *bishse@mail.nih.gov.*

Mouse Monoclonal Antibodies to MAD1, a Human Spindle Assembly Checkpoint Protein for Maintaining Chromosomal Segregation

Description of Technology: Scientists at the National Institutes of Health have developed mouse monoclonal antibodies against the human spindle assembly checkpoint protein, MAD1. The spindle assembly checkpoint in mitotic cell division regulates the fidelity of chromosome segregation during cell division. MAD1 is an important component of this checkpoint control, which if compromised, can lead to the initiation of cancer cell growth. These monoclonal antibodies are the first available antibodies against MAD1 and can be used in laboratory research and diagnostics.

Applications:

- Research tool in various laboratory procedures to identify and detect MAD1.
- Diagnostic tool for aneuploidy, the condition of having an abnormal number of chromosomes, which results in birth and developmental defects, such as Down syndrome.

Inventor: Kuan-Teh Jeang (NIAID).

Publication: K Haller *et al.* The N-terminus of rodent and human MAD1 confers species-specific stringency to spindle assembly checkpoint. Oncogene 2006 Apr 6;25(15):2137–2147.

Patent Status: HHS Reference No. E–119–2003/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Samuel E. Bish, PhD; 301–435–5282; *bishse@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID Office of Technology Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize reagents for studying cell cycle checkpoint factors. Please contact Agnes Rooke at *rookeab@niaid.nih.gov* or by phone at 301–594–1697 for more information.

Dated: January 30, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–2821 Filed 2–10–09; 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.

Prognostic Test for Breast Cancer Based on a 12 Gene Expression Signature

Description of Technology: The clinical course and survival times of patients with breast cancer varies greatly, consequently it is difficult to establish a prognosis for the disease. To improve patient prognosis, much effort has been made to identify biological markers that would allow precise staging of the cancer. When cells cannot repair minor damage to their DNA it leads to genetic instability which can produce gross abnormalities in chromosomes and the onset of a cancer. It is known that the magnitude of the abnormalities is strongly correlated with a negative prognosis for cancer. Thus, genetic instability can serve as a useful biomarker for establishing a prognosis for breast cancer patients. Presently, genetic instability is not directly accounted for in established prognostic tests.

Investigators at the National Cancer Institute (NCI) have developed a compact gene signature that detects genome instability in breast cancer cells. By comparing changes in expression levels of only 12 genes in malignant tissue to levels in normal breast tissue it is possible to detect the genetic abnormalities that are indicative of a poor prognosis. This method has potential to improve markedly the forecasting of clinical outcomes for breast cancer and help improve treatment of this disease.

Applications:

- Precise staging of women with breast cancer prior to commencing treatment.

• Discovery of therapeutics that alter genomic instability and improve breast cancer prognosis.

Advantages:

• Reduced number of genes to measure compared to available technologies.

• Prognosis independent of other cancer indicators, such as lymph node status.

• Improved prediction in low risk patients.

Market: It is estimated that in 2008 more than 184,000 Americans would be diagnosed with breast cancer. After lung cancer, breast cancer is the second most lethal cancer in women.

Development Status: Pre-clinical or clinical data available.

Inventors: Thomas Ried (NCI) *et al.*

Publications: Presently, none related to this invention.

Patent Status: U.S. Provisional Application No. 61/097,101 filed 15 Sep 2008 (HHS Reference No. E–215–2008/0-US–01).

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

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

Collaborative Research Opportunity: The National Cancer Institute Genetics Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Prognostic Test for Breast Cancer Based on a 12 Gene Expression Signature. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

HMGN Polypeptides as Immune Enhancers and HMGN Antagonists as Immune Suppressants

Description of Technology: HMGN polypeptides are multidomain proteins known to function by binding DNA to regulate the transcription of certain genes inside cells. However, when a HMGN polypeptide is released extracellularly, it distinctly acts as a potent activator of the immune system. Because of this activity, it has potential use as a biological therapeutic for stimulating an immune response as well as a promising target for antagonist drugs to suppress a pathological inflammatory response.

Secreted HMGN acts as a potent recruiter and activator of dendritic cells, the cell principally responsible for initiating the immune response. Furthermore, it enables dendritic cells to preferentially induce a Th1-type T lymphocyte response that leads to enduring cellular immunity. Therefore, HMGN has potential use as a clinically effective immunoadjuvant for use in vaccines against tumors and many intracellular pathogens.

Investigators at the National Institutes of Health have developed compositions and methods for using HMGN and its derivatives as immunoadjuvants in combination, as mixtures or as chemical conjugates, with microbial or tumor antigens. HMGN has the advantage of being gene encoded so it can be fused to an antigen gene to produce recombinant fusion proteins or administered as a DNA vaccine. Conversely, HMGN could be exploited as a drug target to treat diseases that would benefit from shifting away the Th1-type immune response towards a Th2-type or humoral immune response. This would be beneficial for treatment of parasitic infections and inflammatory or autoimmune disorders.

Applications:

• As an immunostimulatory adjuvant to increase efficacy of preventive or therapeutic vaccinations against microbes or cancers.

• As an attractant and activator of dendritic cells.

• Antagonist drug development for suppressing Th1-type response.

Advantages:

• Less adverse effects expected compared to current immunoadjuvants since HMGN is produced by the human body.

• Highly effective polarizer of the immune response towards Th1-type immunity.

Development Status: Pre-clinical data available.

Market: Very few immunoadjuvants have reached clinical approval since the introduction of alum over half a decade ago. Currently, there is a need for safe and effective vaccine adjuvants to increase the effectiveness of preventive and therapeutic vaccines.

Inventors: De Yang *et al.* (NCI).

Publications: Presently, none related to this invention.

Patent Status: U.S. Provisional Patent No. 61/083,781 filed 25 Jul 2008 (DHHS Reference No. E–185–2008/0-US–01).

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

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

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Molecular Immunoregulation is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HMGN1. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Substituted IL–15

Description of Technology: Interleukin-15 (IL–15) is an immune system modulating protein (cytokine) that stimulates the proliferation and differentiation of T-lymphocytes. In the clinical context, IL–15 is being investigated for use in the treatment of diseases such as cancer. In vitro manufacture of IL–15 can be problematic.

The invention relates to substituted IL–15 amino acid sequences of one or more amino acids that are predicted to reduce or eliminate deamidation of a specific aspargine amino acid residue found within the IL–15 protein. Deamidation can lead to protein degradation and interfere with the pharmaceutical purification and processing of IL–15. The invention also provides potential substituted gene sequences that encode the substituted IL–15 amino acid sequences. The substituted IL–15 amino acid sequences may advantageously facilitate the refolding, purification, storage, characterization, and clinical testing of IL–15.

Applications: IL–15 immunotherapies.

Advantages: Potential decreased immunogenicity of pharmacologically active IL–15 expressed in *E. coli.*

Development Status: Concept Development Phase.

Market: Cancer immunotherapy; IL–15 based immunotherapies.

Inventors: David F. Nellis *et al.* (NCI/SAIC).

Patent Status: U.S. Provisional Application No. 61/049,165 filed 30 Apr 2008 (HHS Reference No. E–123–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute Biological Research Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the topic of this U.S. Provisional Patent Application. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Novel Protein Delivery System for Mammalian Cells

Description of Technology: Virus-like particles (VLPs) consist of viral structural proteins that are capable of

self-assembly into a nanoparticle, but are non-infectious because they lack viral nucleic acids. VLPs have been used in viral vaccines, such as those for human papilloma virus and hepatitis B. However, they also have great potential in other applications, such as cancer vaccines, transport of nucleic acids into target cells (gene therapy), and transport of biologics or other large molecules into target cells for therapeutic purposes. The present technology discloses a chimeric VLP containing a GAG-Cre recombinase fusion protein. This recombinase fusion protein retains Cre recombinase activity, and can excise a LOX-flanked gene in a transduced target cell. Experiments by Drs. Kaczmarczyk and Chatterjee have demonstrated that chimeric VLPs can be used to deliver functional fusion proteins into cells. The technology also provides for a two-VLP protein delivery system designed to deliver a protein of interest into a target cell. The present technology also discloses VLPs containing GAG-protein of interest (ex. GAG-Cre) co-packaged with GAG-protease to deliver protein of interest in target site as a fully-processed protein rather than as a fusion protein.

The claims in the pending patent application provide for virus-like particles, methods of making virus-like particles, and methods of using virus-like particles to deliver proteins to a cell. The claims also provide for methods of targeting a protein to a cell, methods of protein therapy and methods of treating diseases or disorders.

Applications:

- Intracellular targeted delivery of therapeutic proteins.
- *Ex vivo* use for expansion of stem cells for transplantation.
- Antigen loading of dendritic cells for cancer vaccination.

Market: The therapeutic protein market segment will have a projected $52.2 billion in sales in 2010.

Development Status: In vivo feasibility studies are in progress.

Patent Status: U.S. Patent Application No. 61/195,084 filed 03 Oct 2008 (HHS Reference No. E–010–2008/0–US–01).

Inventors: Deb K. Chatterjee and Stanislaw J. Kaczmarcyk (NCI/SAIC).

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Advanced Technology Program, Protein Expression Laboratory, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: January 30, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–2822 Filed 2–10–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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 meeting.

The meeting 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Islet Cell Distribution Coordinating Center.

Date: March 23, 2009.

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

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn National Airport Hotel, 2650 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Michael W. Edwards, PhD., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8886, *edwardsm@extra.niddk.nih.gov.* (Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 4, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–2824 Filed 2–10–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Institute of Mental Health Special Emphasis Panel; Time-Sensitive Review.

Date: February 20, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Trauma in High-Risk Occupations.

Date: March 6, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Serena P. Chu, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Rockville, MD 20892–9609, 301–443–0004, *sechu@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Fellowships and Dissertation Grants.

Date: March 10, 2009.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.