h. A statement as to whether or not information that could identify the donor(s) would be retained prior to the derivation or the use of the human embryonic stem cells (relevant guidance from the DHHS Office for Human Research Protections (OHRP) should be followed, as applicable; see OHRP's *Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles* and *Guidance on Research Involving Coded Private Information or Biological Specimens,* or successor guidances); and

i. A statement that the results of research using the human embryonic stem cells may have commercial potential, and a statement that the donor(s) would not receive financial or any other benefits from any such commercial development.

C. Prior to the use of NIH funds: Funding recipients must ensure that: (1) The human embryonic stem cells were derived consistent with sections II.A and B of these Guidelines; and (2) the grantee institution maintains appropriate documentation demonstrating such consistency in accordance with 45 CFR 74.53, which also details rights of access by NIH. The responsible grantee institutional official must provide assurances with respect to (1) and (2) when endorsing applications and progress reports submitted to NIH for projects that utilize these cells.

III. Research Using Human Embryonic Stem Cells and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come From Allowable Sources, Is Nevertheless Ineligible for NIH Funding

This section governs research using human embryonic stem cells and human induced pluripotent stem cells, *i.e.,* human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. There are some uses of these cells that, although they may come from allowable sources, are nevertheless ineligible for NIH funding, as follows:

A. Research in which human embryonic stem cells (even if derived according to these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.

B. Research involving the breeding of animals where the introduction of human embryonic stem cells (even if derived according to these Guidelines) or human induced pluripotent stem cells may have contributed to the germ line.

IV. Other Non-Allowable Research

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Consolidated Appropriations Act, 2009, Pub. L. 110–161, 3/11/09), otherwise known as the Dickey-Wicker Amendment.

B. NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not allowed under these Guidelines.

Dated: April 17, 2009.

Raynard S. Kington,

Acting Director, NIH.

[FR Doc. E9–9313 Filed 4–22–09; 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.

On-Demand In Vitro Assembly of Protein Microarrays

Description of Technology: Protein microarrays are becoming an indispensable biomedical tool to facilitate rapid high-throughput detection of protein-protein, protein-drug and protein-DNA interactions for large groups of proteins. The novel Protein Microarray of this invention is essentially a DNA microarray that becomes a protein microarray on demand and provides an efficient systematic approach to the study of protein interactions and drug target identification and validation, thereby speeding up the discovery process. The technology allows a large number of proteins to be synthesized and immobilized at their individual site of expression on an ordered array without the need for protein purification. As a result, proteins are ready for subsequent use in binding studies and other analysis.

The Protein Microarray is based on high affinity and high specificity of the protein-nucleic acid interaction of the Tus protein and the Ter site of E. coli. The DNA templates are arrayed on the microarray to perform dual function: (1) Synthesizing the protein in situ (cell-free protein synthesis) in the array and (2) at the same time capturing the protein it synthesizes by DNA-protein interaction. This method utilizes an expression vector containing a DNA sequence which serves a dual purpose: (a) Encoding proteins of interest fused to the Tus protein for in vitro synthesis of the protein and (b) encoding the Ter sequence, which captures the fusion protein through the high affinity interaction with the Tus protein.

Applications:

- Simultaneous analysis of interactions of many proteins with other proteins, antibodies, nucleic acids, lipids, drugs, etc, in a single experiment.
- Efficient discovery of novel drugs and drug targets.

Development Status: The technology is in early stages of development.

Inventors: Deb K. Chatterjee, Kalavathy Sitaraman, James L. Hartley, David J. Munroe, Cassio Baptista (NCI).

Patent Status:

U.S. Patent Application No. 11/252,735 filed 19 Oct 2005 (HHS Reference No. E–244–2005/0–US–01).

U.S. Patent Application No. 12/105,636 filed 18 Apr 2008 (HHS Reference No. E–244–2005/1–US–02).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; *jeffreyja@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Protein Expression Laboratory is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or

commercialize in vitro assembly of protein microarrays. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Methods and Compositions for High-Throughput Detection of Protein/Protein Interactions Ex Vivo

Description of Technology: This invention relates to methods and compositions for the high-throughput detection of protein-protein interactions using a lambda phage display system. One of the central challenges in systems biology is defining the interactome, or set of all protein-protein interactions within a living cell, as a basis for understanding biological processes for early diagnosis of disease and for drug development. The invention provides a novel proteomic toolbox for high-throughput medical research based in combining phage lambda protein display and recent advances in manipulation of the phage's genome. The method uses the bacteriophage lambda vector to express proteins on its surface, and is based on the use of mutant phage vectors such that only interacting phages will be able to reproduce and co-infect an otherwise non-permissive host and produce plaques.

Application: The invention allows for the characterization of bacteriophage display libraries that could be easily adapted to be used in large-scale functional protein chip assays.

Inventors: Sankar Adhya and Amos Oppenheim (NCI).

Patent Status: U.S. Patent Application No. 11/719,925 filed 22 May 2007 (HHS Reference No. E–264–2004/0–US–03).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov.*

Therapeutic Methods Based on In Vivo Modulation of the Production of Interferon Gamma

Description of Technology: The technology offered for licensing is in the field of Therapeutics. More specifically, the technology relates to biological ligands and their use as modulators of the production of Interferon gamma as a means to treat a broad spectrum of diseases. The invention describes and claims antibodies and other ligands that can stimulate Natural Killer (NK) immune cells to produce Interferon gamma which contributes to the combat against foreign pathogens. Conversely, the invention also describes and claims methods that can inhibit such Interferon gamma production for treatment of diseases where excess of Interferon is not desirable. The invention also describes methods and assays to identify both inducing and inhibiting ligands.

The license agreement may include biological materials, such as monoclonal antibodies that were made and identified by the inventors as Interferon gamma stimulators.

Interferon-gamma is a potent antiviral and antimicrobial substance produced by natural killer (NK) white blood cells. NK cells are activated during infections by viruses and by other intracellular pathogens, such as parasites and bacteria. Soluble substances, such as interleukins, produced by infected cells activate NK cells to secrete interferon-gamma. Injection of interleukins into patients to stimulate NK cells to secrete interferon-gamma has not been a successful therapeutic approach because of the toxicity involved. The invention is based on the discovery by the inventors that activation of the KIR2DL4 receptor expressed by all NK cells stimulates them to produce interferon-gamma. The invention claims monoclonal antibodies and derivatives thereof, as well as natural and synthetic ligands of KIR2DL4 that can be utilized to stimulate interferon-gamma production by NK cells without any other stimulus. The possibility of inducing interferon-gamma production by NK cells without the toxic side effects of interleukins could be an effective therapy for various types of infections and of cancers. Also claimed in the invention are methods of treating various cancers and viral infections, methods of treating autoimmune disease, and methods of administration of the antibody or derivatives thereof. Certain diseases benefit from reduction in the amount of Interferon gamma. The instant invention claims such ligands that are capable of inhibiting KIR2DL4 from producing interferon gamma. It also describes methods of identifying such ligands.

Applications:

- Therapeutics of infectious diseases, cancer and autoimmune diseases
- The mAbs can be used as research reagents

Advantages: Absence of toxicity as compared with current methods such as IL–2 treatment.

Development Status: The inventors generated monoclonal antibodies that have demonstrated stimulation of Interferon gamma production. Proof of concept has been demonstrated.

Market: The technology lends itself to treatment of viral and microbial-caused infectious disease and possibly as therapy for certain cancers and autoimmune disease. Collectively, these medical areas represent a huge market of multi billion dollars and thus significant commercial opportunities.

Inventors: Eric O. Long and Sumati Rajagopalan (NIAID).

Relevant Publications:

1. S Rajagopalan, J Fu, EO Long. Cutting edge: induction of IFN-gamma production but not cytotoxicity by the killer cell Ig-like receptor KIR2DL4 (CD158d) in resting NK cells. J Immunol. 2001 Aug 15;167(4):1877–1881.

2. A Kikuchi-Maki, TL Catina, KS Campbell. Cutting edge: KIR2DL4 transduces signals into human NK cells through association with the fc receptor gamma protein. J Immunol. 2005 Apr 1;174(7):3859–3863.

3. S Rajagopalan, YT Bryceson, SP Kuppusamy, DE Geraghty, A van der Meer, I Joosten, EO Long. Activation of NK cells by an endocytosed receptor for soluble HLA–G. PLoS Biol 2006 Jan;4(1):e9.

Patent Status: U.S. Patent 7,435,801 issued 14 Oct 2008 (HHS Reference No. E–255–2000/0–US–03); U.S. Patent Application No. 12/249,703 filed 10 Oct 2008 (HHS Reference No. E–255–2000/0–US–04); both entitled ''Antibodies and Other Ligands Directed Against KIR2DL4 Receptor for Production of Interferon-Gamma''.

Licensing Status: Available for licensing. Monoclonal antibodies made by the inventors and identified as stimulators may be available and provided with the license agreement.

Licensing Contacts: Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov;* Rung C. Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov.*

Dated: April 17, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–9348 Filed 4–22–09; 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