anthrax vaccine. Proc Natl Acad Sci USA. 2003 Jul 22;100(15):8945–8950.

Patent Status: U.S. Patent Application No. 10/559,825 filed 02 Dec 2005, claiming priority to 05 Jun 2003 (HHS Reference No. E–343–2002/0–US–04).

Licensing Status: Available for licensing.

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

Improved Bacterial Host for Production of Anthrax Toxin Proteins and Vaccines: *Bacillus anthracis* BH450

Description of Invention: Anthrax toxin has previously been made from various avirulent strains of *Bacillus anthracis*. The inventors have genetically engineered a new strain of *B. anthracis* with improved properties. The strain, designated BH450, is totally deficient in the ability to make spores and to produce a major extracellular protease designated Peptidase M4. The genetic lesions introduced are defined, true deletions, so there is no possibility of reversion. Inability to make spores assures that laboratories growing the strain will not become contaminated with the very stable anthrax spores. Inability to make peptidase M4 increases the stability of proteins such as anthrax toxin that are secreted to the culture medium.

Applications and Modality: B. anthracis vaccine/prophylactic and therapeutic studies.

Market: Research tool useful for biodefense/therapeutic studies.

Development Status: The technology is a research tool.

Inventors: Andrei Pomerantsev, Dana Hsu, Ramakrishnan Sitaraman, Craig Galloway, Violetta Kivovich, Stephen Leppla (NIAID).

Publication: AP Pomerantsev *et al.* Genome engineering in Bacillus anthracis using Cre recombinase. Infect Immun. 2006 Jan;74(1):682–693.

Patent Status: HHS Reference No. E–127–2007/0—Research Tool.

Licensing Status: This technology is not patented. The strain will be transferred through a Biological Materials License.

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

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Bacterial Diseases, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize *Bacillus anthracis* BH450 strain. Please contact Dr. Andrei P. Pomerantsev at phone 301/451–9817 and/or e-mail *apomerantsev@niaid.nih.gov* for more information.

Monoclonal Antibodies That Neutralize *B. anthracis* Protective Antigen (PA), Lethal Factor (LF) and Edema Factor (EF)

Description of Invention: Anthrax, whether resulting from natural or bioterrorist-associated exposure, is a constant threat to human health. The lethality of anthrax is primarily the result of the effects of anthrax toxin, which has 3 components: a receptor-binding protein known as ''protective antigen'' (PA) and 2 catalytic proteins known as ''lethal factor'' (LF) and ''edema factor'' (EF). Although production of an efficient anthrax vaccine is an ultimate goal, the benefits of vaccination can be expected only if a large proportion of the population at risk is immunized. The low incidence of anthrax suggests that large-scale vaccination may not be the most efficient means of controlling this disease. In contrast, passive administration of neutralizing human or chimpanzee monoclonal antibody to a subject at risk for anthrax or exposed to anthrax could provide immediate efficacy for emergency prophylaxis against or treatment of anthrax.

Four monoclonal antibodies (mAbs) against PA, three mAbs against LF and four mAbs specific for EF of anthrax were isolated from a phage display library generated from immunized chimpanzees. Two mAbs recognizing PA (W1 and W2), two anti-LF mAbs efficiently neutralized the cytotoxicity of lethal toxin in a macrophage lysis assay. One anti-EF mAb efficiently neutralized edema toxin in cell culture. All five neutralizing mAbs protected animals from anthrax toxin challenge.

Application: Prophylactics or therapeutics against *B. anthracis*.

Developmental Status: Preclinical studies have been performed.

Inventors: Zhaochun Chen, Robert Purcell, Suzanne Emerson, Stephen Leppla, Mahtab Moyeri (NIAID).

Publication: Z Chen *et al.* Efficient neutralization of anthrax toxin by chimpanzee monoclonal antibodies against protective antigen. J Infect Dis. 2006 Mar 1;193(5):625–633.

Patent Status: PCT Application No. PCT/US2008/054609 filed 21 Feb 2008, claiming priority to 23 Feb 2007 (HHS Reference No. E–123–2007/0–PCT–02); U.S. Patent Application No. 11/793,735 filed 22 Jun 2007 (HHS Reference No. E–146–2004/0–US–03)

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

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

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Chimpanzee/human neutralizing monoclonal antibodies against anthrax toxins. Please contact Dr. Robert Purcell at 301/496–5090 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. E8–22608 Filed 9–25–08; 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.

Inhibitors of the Plasmodial Surface Anion Channel as Antimalarials

Description of Technology: The inventions described herein are antimalarial small molecule inhibitors of the plasmodial surface anion channel (PSAC), an essential nutrient acquisition ion channel expressed on human

erythrocytes infected with malaria parasites. These inhibitors were discovered by high-throughput screening of chemical libraries and analysis of their ability to kill malaria parasites in culture. Two separate classes of inhibitors were found to work synergistically in combination against PSAC and killed malaria cultures at markedly lower concentrations than separately. These inhibitors have high affinity and specificity for PSAC and have acceptable cytotoxicity profiles. Preliminary *in vivo* testing of these compounds in a mouse malaria model is currently ongoing.

Applications: Treatment of malarial infections.

Advantages: Novel drug treatment for malarial infections; Synergistic effect of these compounds on PSAC.

Development Status: In vitro and *in vivo* data can be provided upon request.

Market: Treatment of malarial infection.

Inventor: Sanjay A. Desai (NIAID).

Publications:

1. Kang M, Lisk G, Hollingworth S, Baylor SM, Desai SA. Malaria parasites are rapidly killed by dantrolene derivatives specific for the plasmodial surface anion channel. Mol. Pharmacol. 2005 Jul;68(1):34–40.

2. Desai SA, Bezrukov SM, Zimmerberg J. A voltage-dependent channel involved in nutrient uptake by red blood cells infected with the malaria parasite. Nature. 2000 Aug 31;406(6799):1001–1005.

Patent Status: U.S. Provisional Application No. 61/083,000 filed 23 Jul 2008 (HHS Reference No. E–202–2008/0–US–01).

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

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@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 antimalarial drugs that target PSAC or other parasite-specific transporters. Please contact either Charles Rainwater or Dana Hsu at 301–496–2644 for more information.

Aerosolized Vaccines

Description of Technology: Vaccine delivery to humans by mucosal routes may offer some operational and immunological advantages over intramuscular administration by needle-and-syringe. Potential targets include the oral, nasal, rectal conjunctival, and vaginal surfaces with the oral and nasal routes being the most practical to consider for infants, children and adults of both sexes. Needle-free delivery methods may improve compliance, reduce discomfort, and improve safety of vaccines; particularly in the developing world, needle-free delivery could mitigate the risk of blood-borne pathogen transmission by unsafe injection practices or inadequately sterilized equipment, and be easier and safer to deploy by non-medical personnel.

Mucosal vaccination may offer a potential immunological advantage of recruiting mucosal lymphoid tissues that are important in mediation of immune responses, particularly at the entry site for infectious pathogens. Optimally formulated and delivered antigens may elicit a variety of responses in these tissues including secretory IgA, serum IgG capable of neutralizing toxins or viruses, and cell-mediated immunity as measured by cytotoxic T-cell responses and cytokine production.

In the case of respiratory delivery, specific particle sizes can target particular microenvironments within the lung. Efficient penetration of the lung parenchyma depends upon optimizing the size of the droplet in relation to the diameter of the respiratory airways. It has been recommended that school age children and adults be immunized with respiratory particles that are between 3 and 5 μm in diameter, since a larger particle cannot effectively penetrate deep into the lung.

This application claims aerosolized immunogenic compositions comprising aerosolized immunogenic particles between 0.01 μm and 15 μm. The application also claims methods for delivering immunogenic compositions, methods for generating immune responses, and methods for treating infections by producing and administering aerosolized immunogenic compositions. More specifically, the invention claims replication-defective recombinant adenoviruses encoding human immunodeficiency virus (HIV), simian immunodeficiency virus (SIV) and tuberculosis (TB) genes delivered by aerosolization into the lung. The inventors have shown that this regimen induces very high, stable cellular immune responses localized to the lung, as well as humoral responses in the lung, systemically, and, importantly, at distal mucosal sites. This regimen may prove highly useful for vaccination against respiratory infections such as TB, influenza, and respiratory syncytial virus, and provide a platform for generating mucosal antibody responses against other pathogens.

Applications: Improved immunogenic compositions and vaccine formulations, delivery of viral vectors, plasmid DNA, proteins, and adjuvants.

Development Status: Vaccines have been formulated and preclinical studies have been performed.

Inventors: Mario Roederer and Srinivas Rao (NIAID).

Patent Status: U.S. Provisional Application No. 61/038,534 filed 21 Mar 2008 (HHS Reference No. E–053–2008/0–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*.

Use of Saccharides Cross-Reactive With *Bacillus anthracis* Spore Glycoprotein as a Vaccine Against Anthrax

Description of Technology: Bacillus anthracis is a spore-forming bacterium that causes anthrax in humans and in other mammals. The glycoprotein BclA (Bacillus collagen-like protein of anthracis) is a major constituent of the exosporium, the outermost surface of *B. anthracis* spores. The glycosyl part of BclA is an oligosaccharide composed of 2-O-methyl-4-(3-hydroxy-3-methylbutanamido)-4,6-dideoxy-d-glucose, referred to as anthrose, and three rhamnose residues. A structure similar to anthrose, 4-(3-hydroxy-3-methylbutanamido)-4,6-dideoxy-d-glucose is found in the side chain of the capsular polysaccharide (CPS) of *Shewanella* spp. MR–4. Under certain growth conditions the bacteria produce a variant CPS lacking one methyl group on the hydroxybutyrate, 4-(3-hydroxybutanamido)-4,6-dideoxy-d-glucose. Contrary to anthrose, neither of the *Shewanella* CPSs is 2-O methylated.

The inventors have found that both *Shewanella* CPS variants react with anti-*B. anthracis* spore sera. The inventors have also found that these antisera reacted with flagellae of *Pseudomonas syringae*, reported to be glycosylated with a similar terminal saccharide, 4-(3-hydroxybutanamido)-4,6-dideoxy-2-O-methyl-d-glucose. Sera produced by immunization with *Shewanella* or *P. syringae* cells bound to *B. anthracis* spores but not to *Bacillus cereus* spores in a fluorescent microscopy assay. The inventors' experiments show that methylation of the anthrose at the O–2 of the sugar ring and at the C–3 of 3-hydroxybutyrate are not essential for induction of cross-reactive antibodies.

The application claims the use of *Shewanella* CPS conjugates as a component of an anthrax vaccine. The application also claims the use of capsular polysaccharides from *Shewanella* and compounds from the flagella of *Pseudomonas syringae* for the development of anthrax vaccines.

Application: Development of anthrax vaccines, diagnostics and therapeutics.

Development Status: Conjugates have been synthesized and preclinical studies have been performed.

Inventors: Joanna Kubler-Kielb (NICHD), Rachel Schneerson (NICHD), Haijing Hu (NIAID), Stephen H. Leppla (NIAID), John B. Robbins (NICHD), *et al.*

Publication: Kubler-Kielb J. et al. Saccharides cross-reactive with *Bacillus anthracis* spore glycoprotein as an anthrax vaccine component. Proc Natl Acad Sci USA. 2008 Jun 24;105(25):8709–8712. This publication reports the preparation, characterization, and antibody responses to protein conjugates of the two variants of *Shewanella* CPS. Significantly, both conjugates induced antibodies that bound to both *Shewanella* CPS variants by ELISA and to *B. anthracis* spores, as detected by fluorescent microscopy.

Patent Status: U.S. Provisional Application No. 61/066,509 filed 19 Feb 2008 (HHS Reference No. E–032–2008/0-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.*

Modified Sugar Substrates and Methods of Use

Description of Technology: Glycans can be classified as linear or branched sugars. The linear sugars are the glycosaminoglycans comprising polymers of sulfated disaccharide repeat units that are O-linked to a core protein, forming a proteoglycan aggregate. The branched glycans are found as N-linked and O-linked sugars on glycoproteins or on glycolipids. These carbohydrate moieties of the linear and branched glycans are synthesized by a super family of enzymes, the glycosyltransferases (GTs), which transfer a sugar moiety from a sugar donor to an acceptor molecule. Although GTs catalyze chemically similar reactions in which a monosaccharide is transferred from an activated derivative, such as a UDP-sugar, to an acceptor, very few GTs bear similarity in primary structure.

Eukaryotic cells express several classes of oligosaccharides attached to proteins or lipids. Animal glycans can be N-linked via beta-GlcNAc to Asparagine (N-glycans), O-linked via UDP-GalNAc to Serine/Threonine (O-glycans), or can connect the carboxyl end of a protein to a phosphatidylinositol unit (GPI-anchors) via a common core glycan structure. Thus, there is potential to develop carbohydrate substrates comprising bioactive agents that can be used to produce glycoconjugates carrying sugar moieties with bioactive agents. Such glycoconjugates have many therapeutic and diagnostic uses, e.g. in labeling or targeted delivery. Further, such glycoconjugates can be used in the assembly of bio-nanoparticles to develop targeted-drug delivery systems or contrast agents for medical uses.

This application claims methods and compositions for making and using functionalized sugars. Also claimed in the application are methods for forming a wide variety of products at a cell or in an *in vitro* environment. More specifically, the claimed compositions of the invention comprise a sugar nucleotide and one or more functional groups.

Applications: Production of therapeutic or diagnostic glycoconjugates, assembly of bio-nanoparticles, development of contrast agents.

Development Status: Enzymes have been synthesized and initial studies have been performed.

Inventors: Pradman K. Qasba and Maria R. Manzoni (NCI).

Publications:

1. B Ramakrishnan et al. Applications of glycosyltransferases in the site-specific conjugation of biomolecules and the development of a targeted drug delivery system and contrast agents for MRI. Expert Opin Drug Deliv. 2008 Feb;5(2):149–153. Review.

2. PK Qasba et al. Site-specific linking of biomolecules via glycan residues using glycosyltransferases. Biotechnol Prog. 2008 May-Jun;24(3):520–526.

Patent Status: U.S. Patent Application No. 61/027,782 filed 11 Feb 2008 (HHS Reference No. E–016–2008/0–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*.

Collaborative Research Opportunity: The National Cancer Institute's Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the synthesis of UDP derivatives of C2 modified galactose for use as donor substrates for glycosyltransferases. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Immunogenic Peptides Against Influenza Virus

Description of Technology: The invention described herein are peptides and polypeptides derived from the HA, NA, PB2, PB1, PA, M1, M2, NP, NS1, and NS2 proteins of influenza virus that elicit immunogenic responses; particularly neutralizing antibodies, against human and avian influenza strains H1N1, H3N2, H5N1 and H7N7. Materials in the form of immunogenic compositions including these peptides and polypeptides can also be in-licensed along with the patent rights. Pharmaceutical compositions including these peptides and polypeptides with or without adjuvants are within the scope of the invention. The inventors are currently investigating the vaccine potential of specific peptides and polypeptides.

Applications:

- Vaccines against influenza virus infection;
- Diagnostics for the detection of influenza virus infection; and
- Generation of influenza virus specific antibodies.

Advantages:

- Peptides can be expressed in a number of different expression systems; and
- Peptides were identified based on the specificity of antibodies derived from human and avian influenza virus infected individuals.

Development Status: In vitro data can be provided upon request.

Market:

- Preventative or treatment for influenza virus infection; and
- Diagnostic for influenza virus infection.

Inventors: Hana Golding and Surender Khurana (FDA).

Publications:

1. Pandemic Influenza preparedness: New molecular tools for evaluation of influenza vaccines and identification of serological epitopes for avian influenza diagnostic assays at ''Options for the Control of Influenza VI'' June 17–23, 2007, Toronto, Canada. (oral presentation)

2. Pandemic Influenza preparedness: Identification of serological epitopes for use in development of broadly cross-reactive influenza vaccines at ''National Foundation for Infectious Diseases—11th Annual Conference on Vaccine Research'', Baltimore: May 5–7, 2008. (oral presentation).

3. Analysis of antibody repertoires in H5N1 infected and vaccinated

individuals using influenza whole genome phage display at ''Immunobiology and Pathogenesis of Influenza Infection'', Atlanta: June 1–3, 2008. (poster presentation).

Patent Status: International Patent Application PCT/US2008/067001 filed 13 Jun 2008 (HHS Reference No. E–236–2007/3–PCT–01).

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

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

Collaborative Research Opportunity: The FDA, Center for Biologics Evaluation and Research (CBER), Division of Viral Products, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these peptides as vaccine candidates or diagnostics. Please contact Alice Welch at *alice.welch@fda.hhs.gov* or 301–827–0359 for more information.

A Rapid Ultrasensitive Assay for Detecting Prions Based on the Seeded Polymerization of Recombinant Normal Prion Protein (rPrP-sen)

Description of Technology: Prion diseases are neurodegenerative diseases of great public concern because humans may be infected from hoofed animals used as food, food products such as milk, or blood products. Currently available tests for disease-causing prions are either incapable of detecting low concentrations of prions and must be used post-mortem or are incapable of detecting low concentrations of prions economically or accurately. This technology enables rapid and economical detection of sub-lethal concentrations of prions by using recombinant, normal, prion protein (rPrP-sen) as a marker or indicator of infectious prions in a sample. Specifically, prions (contained in a sample) seed the polymerization of rPrP-sen, and polymerized rPrP-sen is detected as an amplified indicator of prions in the sample. This assay differs from the protein-misfolding cyclic amplification assay (PMCA) because it enables the effective use of rPrP-sen and does not require multiple amplification cycles unless a higher degree of sensitivity is required. It is anticipated that this technology can be combined with additional prion-detection technologies to further improve the sensitivity of the assay. In its current embodiment, this assay has been used to detect prions in brain tissue or cerebral spinal fluid (CSF) from humans (variant CJD), sheep (scrapie), and hamsters (scrapie).

Advantages:

- Uses a consistent, concentrated source of normal prion protein (rPrP-sen)
- Prions are detectable to low levels after a single amplification round
- May be combined with complimentary detection technologies to improve sensitivity
- Demonstrated to be effective at detecting prions from different species
- May be applicable to blood products
- Economical

Applications:

- A test for live animals or food products
- A human diagnostic for early detection of prion diseases
- Monitor for effectiveness of treatments or disease progression

Inventors: Byron W. Caughey, Ryuichiro Atarashi, Roger A. Moore, and Suzette A. Priola (NIAID).

Related Publications:

1. R Atarashi et al. Simplified ultrasensitive prion detection by recombinant PrP conversion with shaking. Nat Methods 2008 Mar;5(3):211–212.

2. R Atarashi et al. Ultrasensitive detection of scrapie prion protein using seeded conversion of recombinant prion protein. Nat Methods 2007 Aug;4(8):645–650.

Patent Status:

- PCT Application No. PCT/US2008/070656 filed 21 Jul 2008 (HHS Reference No. E–109–2007/1–PCT–01).
- U.S. Application No. 12/177,012 filed 21 Jul 2008 (HHS Reference No. E–109–2007/1–US–02).

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

Licensing Contact: RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID Laboratory of Persistent Viral Diseases, TSE/Prion Biochemistry Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Rosemary Walsh at 301–451–3528 or *rcwalsh@niaid.nih.gov*.

Dated: September 18, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–22610 Filed 9–25–08; 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; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, October 17, 2008, 2:30 p.m. to 3:30 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on September 11, 2008, 73 FR 0177.

This meeting will be held October 22, 2008 instead of October 17, 2008. The meeting is closed to the public.

Dated: September 18, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–22604 Filed 9–25–08; 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Molecular Therapy Core Centers.

Date: October 21, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Michele L. Barnard, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard,