Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The National Institute of Mental Health Data Access Request and Use Certification (previously National Database for Autism Research Data Access Request), 0925–0667, Revision, Expiration Date: 01/31/2016; NIMH, NIH.

Need and Use of Information Collection: NIMH recently received OMB approval for use of the National Database for Autism Research (NDAR) Data Use Certification (DUC) Form. NIMH is interested in renaming this form the ''NIMH Data Access Request and Use Certification (DUC) Form'' and using it to meet the unique data access needs of all NIMH data repositories. The NIMH DUC form is necessary for ''Recipient'' Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from NIMH repositories and datasets for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the NIMH repositories/datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. There are currently three data repositories/sets positioned to use the NIMH DUC form: NDAR, the NIH Pediatric MRI Data Repository (PedsMRI), and the NIMH Clinical Research Datasets (NCRD).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 380.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
NIMH Data Access Request and Use Certification.	Principal Investigators/Research Assistant.	240	1	95/60	380

Dated: May 16, 2013.

Sue Murrin,

Executive Officer, NIMH, NIH.

[FR Doc. 2013–12601 Filed 5–24–13; 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, 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.

FOR FURTHER INFORMATION CONTACT: 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.

Assay for Quantifying Fragile X Mental Retardation-1 Gene Product

Description of Technology: The invention is directed to a fluorescence based assay to quantify the protein product of the Fragile X Mental Retardation-1 (FMR1) gene in a biological sample.

Fragile X syndrome (FXS) is an X-linked genetic disease that is responsible for intellectual disability and is also the most common single gene cause of autism. FXS is typically caused by loss of expression of the FMR1 gene, which codes for an RNA-binding protein called FMRP. FXS patients exhibit a wide spectrum of symptoms with varying degrees of cognitive and psychosocial impairment. The severity of these symptoms correlates well with the levels of FMRP present in the FXS patient. Because the FMR1 gene is silenced in varying degrees, the levels of FMRP in any particular FXS patient could vary greatly.

Scientists at NIDDK and NCATS have developed a sensitive, time resolved fluorescence based assay to quantify FMRP levels in a biological sample. Unlike other assays, the invention assay utilizes two highly-specific antibodies that bind to different sites of FMRP so as to enable precise and reliable quantification. Currently, there is no approved drug to treat FXS. The invention assay can be used as a high throughput screen to identify and evaluate candidate drugs. In addition, the invention assay can be used to assess and/or predict the severity of a patient's condition based on the amount of FMRP present.

Potential Commercial Applications:

- Diagnosis assay
- High throughput screen of drug libraries
- Optimization assay to further develop potential drug candidates

Competitive Advantages:

- Fast, accurate, and reliable assay to quantify FMRP in easy-to-use fluorescence based format
- Adaptable for high throughput use

Development Stage:

- Prototype
- Pilot
- In vitro data available

Inventors: Wei Zheng (NCATS), Karen P. Usdin (NIDDK), Manju Swaroop (NCATS), Daman Kumari (NIDDK)

Intellectual Property: HHS Reference No. E–083–2013/0—US Application No. 61/793,577 filed 15 March 2013

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *lauren.nguyen-antczak@nih.gov.*

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences (NCATS) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Assay for Quantifying Fragile X Mental Retardation-1 Gene Product. For collaboration opportunities, please contact the NCATS Technology Development Coordinator at *NCATSPartnerships@mail.nih.gov.*

A Novel HIV–1 Entry Inhibitor

Description of Technology: The subject invention describes a novel polypeptide comprising a single human CD4 domain (mD1.22) which is highly soluble and stable with significantly higher neutralizing activity and lower non-specific binding to human blood cell lines. More specifically, mD1.22 is highly promising for several applications due to its biophysical properties: (1) For conjugating with cytotoxic molecules for eradication of HIV-infected cells; (2) for generating multi-specific multi-valent HIV inhibitors with high neutralization potency and breadth, and relatively small molecular size; (3) for generating nanobio-sensors for rapid HIV detection; and (4) for studying the biological functions of CD4 in immune responses and HIV entry.

Potential Commercial Applications:

- HIV therapeutics
- Prophylactics
- Detection reagents
- Research reagent

Competitive Advantages:

- Does not show measurable interaction with MHCII.
- Can be solubly expressed in E. coli with high yields leading to decreased production costs.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Dimiter Dimitrov, Weizao Chen, Prabakaran Ponraj (NCI)

Publications:

1. Chen W, et al. Engineered single human CD4 domains as potent HIV–1 inhibitors and components of vaccine immunogens. J Virol. 2011;85(18):9395–405. [PMID 21715496]
2. Chen W, et al. Bifunctional fusion proteins of the human engineered antibody domain m36 with human soluble CD4 are potent inhibitors of diverse HIV–1 isolates. Antiviral Res. 2010;88(1):107–15. [PMID 20709110]
3. Chen W, et al. Human domain antibodies to conserved sterically restricted regions on gpl20 as exceptionally potent cross-reactive HIV–1 neutralizers. Proc Natl Acad Sci USA. 2008;105(44):17121–6. [PMID 18957538]
4. Lagenaur LA, et al. sCD4–17b bifunctional proteins: extremely broad and potent neutralization of HIV–1 Env pseudotyped viruses from genetically diverse primary isolates. Retrovirology 2010 Feb 16;7:11. [PMID 20158904]
5. Saha P, et al. Design and characterization of stabilized derivatives of human CD4D12 and CD4D1. Biochemistry 2011 Sep 20;50(37):7891–900. [PMID 21827143]

Intellectual Property: HHS Reference No. E–033–2013/0—US Provisional Patent Application No. 61/791,885 filed 15 Mar 2013

Related Technologies: HHS Reference No. E–103–2010/1—

- PCT Application No. PCT/US2011/3743961 filed on 20 May 2011
- National stage filing in EP (EP Application No. 11722270.3) and in USA (US Application No. 13/699,535) on 21 Nov. 2012

Licensing Contact: Sally H. Hu, Ph.D., M.B.A.; 301–435–5606; *hus@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize A Novel HIV-1 Entry Inhibitor. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Novel Fusion Proteins for HIV Vaccine

Description of Technology: The subject invention describes novel fusion proteins (CD4i antibody-HIV-1 envelop glycoprotein (gp120)) which can be used as (1) potential vaccine immunogens that could be more efficient than gp120 alone; (2) candidate therapeutics; and (3) research reagents for exploration of HIV–1 gp120 conformational flexibility, elucidation of mechanisms of virus entry, and evasion of immune responses.

Potential Commercial Applications:

- Develop HIV vaccine
- Research reagent
- Research tools to study the conformations flexibility of gp120, the mechanisms of virus entry, and evasion of immune responses

Competitive Advantages:

- The potential vaccine immunogens that could be more efficient than gp120 alone
- Higher affinity with CD4 and antibodies directed against CD4-binding site than gp120 alone

Development Stage:

- Early-stage
- In vitro data available

Inventors: Dimiter Dimitrov and Weizao Chen (NCI)

Publications:

1. Dey B, et al. Characterization of human immunodeficiency virus type 1 monomeric and trimeric gp120 glycoproteins stabilized in the CD4-bound state: antigenicity, biophysics, and immunogenicity. J Virol. 2007 Jun;81(11):5579–93. [PMID 17360741]
2. Dey B, et al. Structure-based stabilization of HIV-1 gp120 enhances humoral immune responses to the induced co-receptor binding site. PLoS Pathog. 2009 May;5(5):el000445. [PMID 19478876]
3. Xiang SH, et al. Mutagenic stabilization and/or disruption of a CD4-bound state reveals distinct conformations of the human immunodeficiency virus type 1 gp120 envelope glycoprotein. J Virol. 2002 Oct;76(19):9888–99. [PMID 12208966]

Intellectual Property: HHS Reference No. E–256–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Sally H. Hu, Ph.D., M.B.A.; 301–435–5605; *hus@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute (NCI) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Novel Fusion Proteins for HIV Vaccine. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov.*

A Novel Human Antibody for Deploying CH2 Based Therapeutics

Description of Technology: The subject invention describes a novel human antibody (anti-CH2 Fab m01m1) which could be used safely in vitro and in vivo for the detection of CH2 (Fc and IgG as well). More specifically, anti-CH2 Fab m01m1 recognizes a conformational epitope on CH2 so it can be used to monitor the conformational changes when CH2 is modified and mutated, as well as to select proper folded isolated CH2 domains. Thus, anti-CH2 Fab m01m1 is a powerful research reagent for developing the CH2-based novel therapeutics (nanoantibodies, nAbs) and for identifying several binders against various antigens from CH2-based libraries.

Potential Commercial Applications:

- Research reagent
- Facilitate the development of CH2-based novel therapeutics
- Can be used as a library for therapeutic candidates

Competitive Advantages: Novel antibody.

Development Stage:

- Early-stage
- In vitro data available

Publications:

1. Prabakaran P, et al. Structure of an isolated unglycosylated antibody C(H)2 domain. Acta Crystallogr D Biol Crystallogr. 2008 Oct; 64(Pt 10):1062–7. [PMID 18931413]
2. Dimitrov DS. Engineered CH2 domains (nanoantibodies). MAbs. 2009 Jan–Feb;1(1):26–8. [PMID 20046570]
3. Gong R, et al. Engineered human antibody constant domains with increased stability. J Biol Chem. 2009 May 22;284(21):14203–10. [PMID 19307178]
4. Xiao X, et al. A large library based on a

novel (CH2) scaffold: identification of HIV-1 inhibitors. Biochem Biophys Res Commun. 2009 Sep 18;387(2):387–92. [PMID 19615335]
5. Wozniak-Knopp G, et al. Stabilisation of the Fc fragment of human IgG1 by engineered intradomain disulfide bonds. PLoS One. 2012;7(1):e30083 [PMID 22272277]

Inventors: Dimiter Dimitrov (NCI) and Rui Gong (formerly NCI).

Intellectual Property: HHS Reference No. E–245–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Sally H. Hu, Ph.D., M.B.A.; 301–435–5606; *hus@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute (NCI) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize A Novel Human Antibody for Deploying CH2 Based Therapeutics. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Methods for Producing Stem Cell-like Memory T cells for Use in T cell-based Immunotherapies

Description of Technology: T cells currently employed for T cell-based immunotherapies are often senescent, terminally differentiated cells with poor proliferate and survival capacity. Recently, however, NIH scientists identified and characterized a new human memory T cell population with stem cell-like properties. Since these T cells have limited quantities in vivo, the scientists have developed methods by which high numbers of these cells can be generated ex vivo for use in T cell-based immunotherapies. Specifically, this technology describes a method for generating the stem cell-like memory T cells by stimulating naive T cells in the presence of inhibitors of GSK-3beta. It also describes a method for obtaining the stem cell-like memory T cells by sorting T cell lymphocytes using flow cytometry. These stem cell-like memory T cells display enhanced proliferation and survival upon transfer, have the multipotent capacity to generate all memory and effector T cell subsets and show increased anti-tumor activity in a humanized mouse tumor model. Consequently, the coupling of T cell receptor or chimeric receptor gene transfer with this method will enable the generation of a large number of memory stem cells with the desired specificity to effectively treat patients with cancer and chronic infectious diseases.

Potential Commercial Applications:

- Ex vivo generation of stem cell-like memory T cells for T cell-based immunotherapy
- Treatment for patients with cancer and chronic infectious diseases

Competitive Advantages:

- Enhanced proliferation and survival upon transfer
- Multipotent capacity to generate all memory and effector T cell subsets
- Increased anti-tumor actovity

Development Stage:

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Luca Gattinoni (NCI), Enrico Lugli (NIAID), Mario Roederer (NIAID), Nicholas Restifo (NCI)

Publications:

1. Gattinoni L, et al. A human T cell memory subset with stem cell-like properties. Nat Med. 2011 Sep 18;17(10):1290–7. [PMID 21926977]
2. Gattinoni L, et al. Wnt signaling arrests effector T cell differentiation and generates CD8+ memory stem cells. Nat Med. 2009 Jul;15(7):808–13. [PMID 19525962]
3. Lugli E, et al. Identification, isolation and in vitro expansion of human and nonhuman primate T stem cell memory cells. Nat Protoc. 2013 Jan;8(1):33–42. [PMID 23222456]

Intellectual Property: HHS Reference No. E–174–2012/0—PCT Application No. PCT/US12/053947 filed 06 Sep 2012

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the use of T memory stem cells for T cell-based immunotherapies. For collaboration opportunities, please contact Luca Gattinoni at *gattinol@mail.nih.gov* or 301–451–6914, or Nicholas Restifo at *restifo@nih.gov* or 301–496–4904.

Dated: May 21, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–12531 Filed 5–24–13; 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. App.), 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; Time-Sensitive Obesity Prevention.

Date: June 24, 2013.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Close Loop Technologies.

Date: July 2, 2013.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elena Sanovich, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, *sanoviche@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Advancing Clinical Research in Primary Glomerular Diseases (UM1).

Date: July 8, 2013.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy