Section 3060 of the 21st Century Cures Act'' to provide clarification of its interpretation of section 520(o)(1)(A)–(D) of the FD&C Act (21 U.S.C. 360j(o)(1)(A)–(D)), as added by the Cures Act, for certain medical software functions that are not medical devices, including software functions that are intended: (1) For administrative support of a health care facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as electronic patient records, or (4) for transferring, storing, converting formats, or displaying data. Section 520(o)(2) of the FD&C Act describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device. FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

On December 8, 2017, FDA announced in the **Federal Register** a draft guidance entitled ''Clinical and Patient Decision Support Software'' (82 FR 57987). FDA is issuing a revised draft guidance, now entitled ''Clinical Decision Support Software,'' after considering comments received on the draft guidance that issued December 8, 2017. This draft guidance provides FDA's risk-based policy for Device CDS software functions in response to comments received.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical Decision Support Software.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*. This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*. Persons unable to download an electronic copy of ''Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400062 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations, guidance, and form have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
314	Applications for FDA Approval to Market a New Drug	0910–0001
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use—Form FDA 356h.	0910–0338

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21000 Filed 9–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Genes, Genomes, and Genetics Integrated Review Group; Therapeutic Approaches to Genetic Diseases Study Section.

Date: October 24, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301–827–7088, *methode.bacanamwo@nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC, 7850 Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 23, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20965 Filed 9–26–19; 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 invention listed below is owned by an agency of the U.S. Government and is available for licensing 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: Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Improvement of Broadly HIV-Neutralizing Antibodies; Anti-HIV–1 Antibody VRC01.23 for Prevention or Treatment of HIV Infection

Description of Technology:

Scientists at NIAID have developed broadly neutralizing antibodies (bNAbs) with enhanced neutralizing activity against HIV–1. Specifically, previously unknown gp120 interactions with a newly elucidated quaternary receptor (CD4)-binding site in the HIV–1 envelope have been discovered by engrafting the extended heavy-chain framework region 3 (FR3) loop of VRC03 onto several potent bNAbs (including VRC01, VRC07 and N6). The new antibodies show improved binding with CD4 by interacting with both binding sites and as a result show improved neutralization of various HIV–1 strains. Furthermore, they show reduced autoreactivity and, as a result, have prolonged *in vivo* half-life.

One of several antibodies that were developed using this technology is VRC01.23. It combines the VRC03 framework 3 alteration, with a G54W mutation in the heavy chain, and a 3 amino acid deletion in the light chain. The modifications improved the potency while reducing the autoreactivity. In particular, VRC01.23 is capable of neutralizing 96% of HIV–1 viruses tested at geometric mean IC50 =0.042 ug/ml, which is ~10-fold more potent than VRC01.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Improving human monoclonal antibodies for HIV treatment or prevention
- New candidates for use as a therapeutic or as a prophylactic

Competitive Advantages:

- Interaction with multiple HIV binding sites
- Reduced autoreactivity when using the VRC03 framework 3 region mutation
- Improved neutralization breadth and potency over existing antibodies
- Extended in vivo half-life

Development Stage:

- Pre-clinical

Inventors: Paolo Lusso, Qingbo Liu, Peter Kwong, Young Do Kwon, and John Mascola, all of NIAID.

Publications: Liu, Qingbo, et al. ''Improvement of antibody functionality by structure-guided paratope engraftment.'' Nature communications 10.1 (2019): 721.

Intellectual Property: HHS Reference No. E–034–2018–0–PCT–01—PCT Application No. PCT/US2019/019021 filed on 21 February 2019.

Licensing Contact: To license this technology, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov,* and reference E–034–2018.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.*

Dated: September 18, 2019.

Wade W. Green,

Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2019–20994 Filed 9–26–19; 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. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Antagonists of Hyaluronan Signaling for Treatment of Airway Diseases, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD), constitute a major health burden in the development word. It is estimated that nearly15.0% of the adult population in the US are affected with such diseases, and the economic cost burden is over $23 billion annually. Unfortunately, the current options for treatment of such diseases are quite limited, consisting only of bronchodilators and inhaled steroids. The need for a novel and more effective class of therapeutics agents is imperative. The subject invention provides for a potentially more specific and effective treatment of airway diseases as compared with existing treatments. It is based on the inhibition of Hyaluronan (HA), a structural polysaccharide that plays a role in the signaling pathway that leads to the