

Time: 10:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Zhihong Shan, Ph.D., MD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205-J, Bethesda, MD 20892, (301) 827-7085, zhihong.shan@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 4, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Understanding and Reducing Cardiovascular Disease in Type 1 Diabetes Mellitus.

Date: July 15, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208-Z, Bethesda, MD 20892, (301) 827-7987, susan.sunnarborg@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for

Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 4, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

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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: Benjamin Hurley; tel. 240-669-5092; benjamin.hurley@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:

FRugally Optimized DNA Octamer (FRODO): DNA Vector and Uses Thereof for Detecting HIV and SIV

Description of Technology

Quantitative polymerase chain reactions (qPCRs) are commonly employed to enumerate genes of interest among particular biological samples. Insertion of PCR amplicons into plasmid DNA is a mainstay for creation of known quantities of target sequences to standardize quantitative PCRs. Typically, one amplicon is inserted into one plasmid construct, the plasmid is then amplified, purified, serially diluted, and then quantified to be used to enumerate target sequences in

unknown samples. As qPCR is often used to detect multiple amplicons simultaneously, individual qPCR standards are often desired to be normalized one to another. Unlike prior methods using separate plasmid constructs for each target sequence, FRODO incorporates eight amplicons into one plasmid construct ensuring equivalent template copy numbers for all amplicons. Amplifying, purifying, diluting and quantifying one plasmid construct rather than eight individual constructs streamlines standard curve qPCR analyses, reducing reagents and simplifying normalization between amplicons.

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

- Clinical Detection, Monitoring of Nucleic Acid Markers of HIV and Immunological Health: FRODO may be used to efficiently quantify target sequences in unknown samples.
- FRODO is a single plasmid containing 8 amplicons which can be used to quantify several different strains of SIV and HIV, cell number equivalents for humans and nonhuman primates, T cell receptor excision circles (humans and nonhuman primates), and bacterial 16S and ampicillin resistance DNA.
- FRODO may offer improved, more affordable, highly-sensitive nucleic acid-based HIV quantification and/or diagnostic response times, enhancing patient treatment and interventions.
- FRODO can be used to quantify levels of bacterial DNA in clinical samples to determine potential sepsis.
- This technology is especially useful in translational HIV research in which human and nonhuman primate models are used to study HIV pathogenesis, informing public health responses.

Competitive Advantages

- A simplified workflow for qPCR testing. Amplifying, purifying, diluting and quantifying one plasmid construct rather than multiple, individual constructs streamlines standard curve qPCR analyses, reducing reagents and simplifying normalization between amplicons.
- At present, there are a number of antibody-based clinical tools that may be used for diagnosing/detecting HIV, but there are fewer products that affordably detect/monitor nucleic acids of HIV within cells, and immunological health, and efficacy of medicaments