

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in maternal immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

- General public;
- advocacy groups, non-profit organizations, and public interest organizations;
- academics, professional societies, and healthcare organizations;
- public health officials and immunization program managers;
- obstetrical care provider groups including all physician and non-physician providers that administer healthcare services to pregnant women, including pharmacists; and
- representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

Dated: August 16, 2016.

Bruce Gellin,

Executive Secretary, National Vaccine Advisory Committee, Deputy Assistant Secretary for Health, Director, National Vaccine Program Office.

[FR Doc. 2016-20525 Filed 8-25-16; 8:45 am]

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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; R18 and R34.

Date: September 15, 2016.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 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; NIDDK Ancillary Studies (R01).

Date: September 15, 2016.

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 Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, yangj@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity.

Date: September 19, 2016.

Time: 2:00 p.m. to 4:00 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: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 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; PAR-13-228: Biomarkers for Diabetes, Digestive, Kidney and Urologic Diseases using NIDDK Biorepository Samples (R01).

Date: September 21, 2016.

Time: 12:00 p.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: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-16-126: High Impact, Interdisciplinary Science in DDK Research Areas (RC2)-CKD.

Date: September 26, 2016.

Time: 12:00 p.m. to 2:00 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: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-15-067: NIDDK Multi-Center Clinical Study Cooperative Agreement (U01): CKD and Mineral Bone Disorders in Children.

Date: September 27, 2016.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

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

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 22, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-20446 Filed 8-25-16; 8:45 am]

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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; NIDDK Ancillary Studies.

Date: September 9, 2016.

Time: 2:00 p.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, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 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; NIDDK DEM Fellowship Grant Applications Review.

Date: October 3, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7791, goterrobinsoc@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-15-067: NIDDK Multi-Center Clinical Study Cooperative Agreement (U01).

Date: October 3, 2016.

Time: 12:00 p.m. to 2:00 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: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-7682, campd@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-16-002: Understanding Barriers and Facilitators to Type 1 Diabetes Management in Adults.

Date: October 6, 2016.

Time: 1:00 p.m. to 4:30 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: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard,

Bethesda, MD 20892-2542, 301-594-7682, campd@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; The NIDDK-KUH-Fellowship Review SEP.

Date: October 7, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 W Kinzie Street, Chicago, IL 60654.

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; The NIDDK-DDK-D Member Conflict SEP.

Date: October 7, 2016.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 W Kinzie Street, Chicago, IL 60654.

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 22, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-20445 Filed 8-25-16; 8:45 am]

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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 and/or co-development 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. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

FOR FURTHER INFORMATION CONTACT:

Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention:

Detection of Colorectal Cancer Using Two Heme-Related Molecules in Human Feces.

Description of Technology:

Mortality from colorectal cancer (CRC) can be reduced by detecting the cancer or its precursor, colorectal adenoma (CRA), so that it can be removed at an early stage. Current tests involve screening stool specimens for blood, especially for hemoglobin. The fecal immunochemical test (FIT) for hemoglobin is positive in stool for about 60% of early-stage and 85% of advanced CRC cases, with a false-positive rate of less than 10%. Assays with better accuracy are still needed.

The subject technology is a novel assay that detects the presence or absence of one or both of two heme-related peptides, X-18565 and X-19549 in stool samples. The presence of one, and especially both, of these peptides within the stool sample indicates a high likelihood that CRC or CRA is present within the patient. X-18565 was detected in 67% of CRC cases and the specificity of X-18565 was 99%, as it was detected in only 1% of control patients who did not have CRC (e.g., false positives). X-19549 was detected in 48% of CRC cases and the specificity of X-19549 was 97%, as it was detected in only 3% of controls patients who did not have CRC (e.g., false positives). The absence of both X-18565 and X-19549 from the stool sample (or extract) indicates a greater than 95% likelihood that CRC or CRA is not present within the patient from which the stool sample is obtained. The assay can be performed on fresh or frozen samples.