

**FOR FURTHER INFORMATION CONTACT:**

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed.

FDA has determined that the following approved drugs meet the redemption criteria:

- PRALUENT (alirocumab) approved July 24, 2015.
- SOLIQUA (insulin glargine and lixisenatide) approved November 21, 2016, and
- JULUCA (dolutegravir and rilpivirine) approved November 21, 2017.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about PRALUENT (alirocumab), SOLIQUA (insulin glargine and lixisenatide), and JULUCA (dolutegravir and rilpivirine), go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: April 4, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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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, 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; CRIC Ancillary Study (R01)

*Date:* May 17, 2018.

*Time:* 3:00 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:* Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 496-9010, [hoffertj@nidddk.nih.gov](mailto:hoffertj@nidddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Pragmatic Research and Natural Experiments.

*Date:* May 18, 2018.

*Time:* 10:00 a.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.nidddk.nih.gov](mailto:barnardm@extra.nidddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-18-012: NIDDK Program Projects (P01).

*Date:* May 24, 2018.

*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:* 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.nidddk.nih.gov](mailto:campd@extra.nidddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; P01 Application Bladder Physiology.

*Date:* May 31, 2018.

*Time:* 2:00 p.m. to 5:00 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:* Ryan G. Morris, Ph.D., Scientific Review Officer, review branch, DEA, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard,

Bethesda, MD 20892-2542, (301) 594-4721, [ryan.morris@nih.gov](mailto:ryan.morris@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: April 4, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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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, 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 Research.

*Date:* May 1, 2018.

*Time:* 1:00 p.m. to 2:30 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, 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.nidddk.nih.gov](mailto:barnardm@extra.nidddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-17-270: NIDDK Central Repositories Non-renewable Samples Access (X01).

*Date:* May 2, 2018.

*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