

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance document entitled “Human Gene Therapy Products Incorporating Human Genome Editing; Draft Guidance for Industry.” The draft guidance document provides recommendations to sponsors developing human gene therapy products incorporating GE of human somatic cells. Specifically, the guidance provides recommendations regarding information that should be provided in an IND application in order to assess the safety and quality of the investigational GE product as required in 21 CFR 312.23. This includes information on product design, product manufacturing, product testing, preclinical safety assessment and clinical trial design.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another human gene therapy draft guidance document entitled “Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Draft Guidance for Industry.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Human Gene Therapy Products Incorporating Human Genome Editing.” 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.

**II. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910-0543.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/> or <https://www.regulations.gov>.

Dated: March 10, 2022.

**Lauren K. Roth,**

*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 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR19-319: NIDDK Central Repositories Non-renewable Sample Access (X01).

*Date:* May 6, 2022.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Najma S. 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](mailto: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: March 11, 2022.

**Miguelina Perez,**

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

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*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Characterization of Islet-derived Extracellular Vesicles for Improved Detection, Monitoring, Classification, and Treatment of Type 1 Diabetes Special Emphasis Panel.

*Date:* April 6, 2022.

*Time:* 12:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.