products with a USP monograph are required to meet the applicable criteria from these USP General Chapters (see section 501(b) of the FD&C Act). Noncompendial products should also be ''essentially free from visible particulates'' as defined in USP General Chapter <790>.

Applying acceptance criteria, such as the criterion outlined in USP General Chapter <790>, is an important component of the overall visible particulate control program, but meeting these acceptance criteria alone is not sufficient to ensure compliance with the applicable CGMP requirements identified above, which cover a broader array of manufacturing practices than product inspection. Full compliance with CGMP requirements is needed to ensure the continued supply of pure, safe, and effective injectable products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Inspection of Injectable Products for Visible Particulates.'' 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 parts 211, 314, and 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0308, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 14, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27351 Filed 12–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFAs (EB–19–002; EB–20–001) Review SEP.

Date: February 11, 2022.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Songtao Liu, MD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, (301) 827–3025, *songtao.liu@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS)

Dated: December 10, 2021.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27340 Filed 12–16–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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: Center for Inherited Disease Research Access Committee CIDR Member Conflict Meeting.

Date: January 14, 2022.

Time: 12:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Room 3184, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, Bldg. 6700B Rockledge Dr., Rm. 3184, 6700B Rockledge Dr., Bethesda, MD 20817, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: December 13, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27341 Filed 12–16–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NIH Electronic Application System for NIH Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide

opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), in the Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Pamela Reed Kearney, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812–C, Bethesda, MD 20817, or call non-toll-free number (301) 402–2512 or Email your request, including your address to: *NIH-CoC-Coordinator@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, REVISION, exp., date 02/28/2023. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: The current CoC system sends system communications and the approved Certificate to the Principal Investigator and the Institutional Official. NIH is adding two optional data fields to the electronic system for the submission and processing of requests for NIH to issue Certificates of Confidentiality (CoCs). The optional data fields will allow the requester to identify another person that receives CoC system communications and the approved Certificate. This request system provides one electronic form to be used by all research organizations that request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of the U.S. Department of Health and Human Services (HHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of research participants to anyone not connected with the research, except in limited circumstances specified in the statute. At NIH, the issuance of CoCs has been delegated to the NIH Office of Extramural Research (OER) in the NIH Office of the Director. NIH received 795 requests for CoCs from January 2020 through December 2020 and expects to receive approximately the same number of requests in subsequent years. NIH has been using an online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes six sections of information collected from research organizations. The information provided is used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC are issued a Certificate of Confidentiality. This system has increased efficiency and reduced burden for both requesters and NIH staff who currently process these requests.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1193.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Life Scientists	795	1	90/60	1193
Total		795		1193

Dated: December 11, 2021.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2021–27298 Filed 12–16–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

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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 Biomedical Imaging and Bioengineering