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[FR Doc. 2024–21570 Filed 9–19–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Sole Source Supplement to the National Association of Councils on Developmental Disabilities (NACDD)

AGENCY: Administration for Community
Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for
Community Living (ACL) is announcing
the award of a sole-source supplement
for the Bridging Aging and Disability
Networks cooperative agreement. ACL's
Office of Supportive and Caregiver
Services (OSCS), Administration on
Aging (AoA) is collaborating with the
Projects of National Significance, the
Administration on Disabilities (AoD) to
provide a \$180,478 supplement to the
Bridging Aging and Disability grant.
This grant is awarded to the NACDD,
who is partnering with the Institute on
Disability and Human Development at
the University of Illinois-Chicago, the
Lurie Institute for Disability Policy at
Brandeis University, The Arc, and US
Aging—the national association
representing and supporting the
network of Area Agencies on Aging
(AAAs) and Title VI Native American
Aging Programs. The goal of the grant is
to strengthen the collaboration between
aging and disability networks to better
support individuals with intellectual
and developmental disabilities (I/DD)
and their family caregivers in future
planning as they age. The supplemental
funding will be used to additionally
support aging caregivers of adults with
I/DD and will enhance the work of the
17 State Consortia teams to more
directly build capacity of AAAs to serve
adults with I/DD as they age and their
aging caregivers. The administrative
supplement for FY 2024 will be in the
amount of \$180,478, bringing the total
award for FY 2024 to \$600,000.00.

FOR FURTHER INFORMATION CONTACT: For
further information or comments
regarding this program supplement,
contact Larissa Crossen, U.S.
Department of Health and Human
Services, Administration for
Community Living, telephone (202)

795–7333; email Larissa.crossen@acl.hhs.gov

SUPPLEMENTARY INFORMATION: The
purpose of the supplemental funding is
to additionally support aging caregivers
of adults with I/DD and will enhance
the work of the 17 State Consortia
teams. A portion of the funding
(estimated 50%) will be used to pay for
existing workplan activities of the
grantee, particularly where there is
overlap in the existing work to bridge
the aging and disability networks to
support aging caregivers of adults with
I/DD. The remainder of the funding
(estimated to be 50%) will be used to
enhance the work of the 17 State
Consortia teams to more directly build
capacity of AAAs to serve adults with
I/DD as they age and their aging
caregivers.

Program Name: Bridging Aging and
Disabilities Networks.

Recipient: NACDD.

Period of Performance: The
supplement award will be issued for the
fourth year of a five-year project period,
September 30, 2024, through September
29, 2025.

Award Amount: \$180,478.

Award Type: Cooperative Agreement.

Statutory Authority: This program is
authorized under the Developmental
Disabilities Assistance and Bill of Rights
Act of 2000, Title I, Subtitle E.

CFDA Number: 93.631 Discretionary
Projects.

Basis for Award: NACDD is currently
funded to carry out the objectives of this
project, Bridging Aging and Disability
Networks, and has completed three
years of work. ACL believes it is in the
best interest of the Federal Government
to supplement the current grantee's
existing project. Establishing a new
grant project at this time would be
potentially disruptive to the current
work already well under way. Further,
it could create unintended duplication
of effort and missed opportunities for
greater coordination between the aging
and disability networks.

Dated: September 16, 2024.

Alison Barkoff,

*Principal Deputy Administrator for the
Administration for Community Living,
performing the delegable duties of the
Administrator and the Assistant Secretary for
Aging.*

[FR Doc. 2024–21498 Filed 9–19–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4165]

Chemical Analysis for Biocompatibility Assessment of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug
Administration (FDA or Agency) is
announcing the availability of the draft
guidance entitled “Chemical Analysis
for Biocompatibility Assessment of
Medical Devices.” FDA is issuing this
draft guidance to describe
recommended methodological
approaches for chemical analysis for
biocompatibility assessment of medical
devices. The biocompatibility of
medical devices is evaluated based on
the duration of exposure and nature of
contact with the body. Chemical
characterization is one approach that
manufacturers can consider when
developing a strategy for the overall
biocompatibility assessment of a device.
This draft guidance is not final nor is it
for implementation at this time.

DATES: Submit either electronic or
written comments on the draft guidance
by November 19, 2024 to ensure that the
Agency considers your comment on this
draft guidance before it begins work on
the final version of the guidance.

ADDRESSES: You may submit comments
on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the
following way:

- *Federal eRulemaking Portal:*
<https://www.regulations.gov>. Follow the
instructions for submitting comments.
Comments submitted electronically,
including attachments, to <https://www.regulations.gov> will be posted to
the docket unchanged. Because your
comment will be made public, you are
solely responsible for ensuring that your
comment does not include any
confidential information that you or a
third party may not wish to be posted,
such as medical information, your or
anyone else's Social Security number, or
confidential business information, such
as a manufacturing process. Please note
that if you include your name, contact
information, or other information that
identifies you in the body of your
comments, that information will be
posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2024-D-4165 for “Chemical Analysis for Biocompatibility Assessment of Medical Devices.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Chemical Analysis for Biocompatibility Assessment of Medical Devices” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: The Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Silver Spring, MD 20993-0002, 301-796-2530, or by email OSEL_CDRH@fda.hhs.gov, Erica Takai at 301-796-6353, or by email at erica.takai@fda.hhs.gov, or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to describe recommended methodological approaches for chemical analysis for biocompatibility assessment of medical devices. The biocompatibility of medical devices is evaluated based on the duration of exposure and nature of contact with the body. Chemical characterization is one approach that manufacturers can consider when developing a strategy for the overall biocompatibility assessment of a device. Chemical characterization can be an alternative to biological testing for evaluating some biocompatibility endpoints. Use of chemical characterization can reduce the time

needed to complete biocompatibility testing, reduce animal testing, generate data on the chemical constituents of a device, and be used to evaluate multiple biocompatibility endpoints at once. FDA and other stakeholders have observed variability in the approaches of individual laboratories performing analytical chemistry testing that has resulted in inconsistent analytical chemistry reports. The recommendations in this guidance are intended to improve the consistency and reliability of analytical chemistry studies.

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 “Chemical Analysis for Biocompatibility Assessment of Medical Devices.” 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Chemical Analysis for Biocompatibility Assessment of Medical Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00020037 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
860, subpart D	De Novo classification process	0910-0844
“Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-Submissions and Early Payor Feedback Request Programs for Medical Devices.	0910-0756

Dated: September 17, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2024-21575 Filed 9-19-24; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 1009 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 Mental Health Special Emphasis Panel; BRAIN UG3/UH3 Novel Tools Review Meeting.

Date: October 24, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Evon Abisaid, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, Rockville, MD 20852, (301) 827-0399 email: *ereifejes@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Silvio O. Conte Centers for Basic Neuroscience or Translational Mental Health Research (P50).

Date: October 30, 2024.
Time: 10:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892-9608 301-443-4525 email: *steinerr@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Early Phase Clinical Trials: Pharma/Device and K Awards.

Date: October 31, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Regina Dolan-Sewell, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd. Bethesda, MD 20852 (240) 796-6785 email: *regina.dolan-sewell@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 17, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-21588 Filed 9-19-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: October 28, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G54, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Hitendra S. Chand, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G54, Rockville, MD 20852, (240) 627-3245, *hiten.chand@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 16, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-21502 Filed 9-19-24; 8:45 am]

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