

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 2, 2021.

Marquita Cullom,
Associate Director.

[FR Doc. 2021–26561 Filed 12–7–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Notice of Meetings**

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of five AHRQ Subcommittee meetings.

SUMMARY: The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will be closed to the public.

DATES: See below for dates of meetings:

1. *Healthcare Safety and Quality Improvement Research (HSQR)*
Date: February 2–3, 2022
2. *Healthcare Effectiveness and Outcomes Research (HEOR)*
Date: February 9–10, 2022
3. *Health System and Value Research (HSVR)*
Date: February 10–11, 2022
4. *Healthcare Research Training (HCRT)*

Date: February 24–25–28, 2022
5. *Healthcare Information Technology Research (HITR)*
Date: February 24–25, 2022

ADDRESSES: Agency for Healthcare Research and Quality (Virtual Review), 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.) Jenny Griffith, Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427–1557.

SUPPLEMENTARY INFORMATION: In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committee. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). 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.

Agenda items for these meetings are subject to change as priorities dictate.

Marquita Cullom,
Associate Director.

[FR Doc. 2021–26545 Filed 12–7–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief

Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–22–004, Research Grants to Prevent Firearm-Related Violence and Injuries.

Dates: April 4–8, 2022.

Times: 8:30 a.m.–5:00 p.m., EDT.

Place: Videoconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Mikel Walters, Ph.D., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341–3717, Telephone: (404) 639–0913; Email: MWalters@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–26576 Filed 12–7–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to

Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)–RFA–OH–22–003, Occupational Safety and Health Training Project Grants.

Date: February 1–2, 2022.

Time: 1:00 p.m.–4:00 p.m., EST.

Place: Video-Assisted Meeting.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Marilyn Ridenour, B.S.N., M.P.H., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505, Telephone: (304) 285–5879; Email: MRidenour@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–26575 Filed 12–7–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1140]

Investigational New Drug Application Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations; Draft Guidance for Sponsor-Investigators; 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 a draft

guidance for sponsor-investigators entitled “IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations.” FDA is publishing this draft guidance to provide sponsor-investigators (hereafter referred to as sponsors) who are interested in developing individualized antisense oligonucleotide (ASO) drug products for a rapidly progressive, severely debilitating, or life-threatening (SDLT) genetic disease (caused by a unique genetic variant or variants), with clinical recommendations for submission of investigational new drug applications (INDs). These recommendations specifically address the following clinical considerations: Ethical and human subject protection, diagnostic and genetic, dosing, administration, safety, and assessment of clinical response to treatment.

DATES: Submit either electronic or written comments on the draft guidance by February 7, 2022 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–2021–D–1140 for “IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations.” 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>.

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