PICOTS	Inclusion	Exclusion
Timing	Duration of followup: ≥1 month; categorized as short term (1 to <6 months), intermediate term (≥6 to <12 months) and long term (≥12 months) following intervention.	<1 month.
Setting	Any	None.
Study design, publication type.	Randomized clinical trials and cohort studies if RCTs are not available..	• Case reports.
	Large (n > 500) case series for serious, rare harms	• Case series (other than large case series for serious, rare harms).
		• Case-control studies, cross-sectional studies.
		• Conference proceedings, editorials, letters, white papers, citations that have not been peer-reviewed.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–00800 Filed 1–14–21; 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 3–4, 2021
2. *Healthcare Effectiveness and Outcomes Research (HEOR)*
   Date: February 10–11, 2021
3. *Health System and Value Research (HSVR)*
   Date: February 11–12, 2021
4. *Health Care Research and Training (HCRT)*
   Date: February 25–26, 2021 & March 1–2, 2021
5. *Healthcare Information Technology Research (HITR)*
   Date: February 25–26, 2021

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.

Dated: January 12, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–00894 Filed 1–14–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0003]

Notice of Availability of a Draft Policy Statement for the Biosafety of Large Animal Study-Related Activities With Brucella abortus and Brucella suis Using Outdoor Containment Spaces

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is opening a public docket to obtain comment on a draft *Brucella* policy statement. This draft policy statement, when finalized, will aid individuals and entities in the development of biosafety plans for outdoor large animal studies involving swine, elk, bison, and cattle to further brucellosis research in a manner that complies with the HHS and U.S. Department of Agriculture (USDA) select agent regulations. In a companion document published in this issue of the **Federal Register**, USDA has proposed the same policy for comment.

DATES: Submit written or electronic comments by March 16, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0003 by either of the methods listed below. Do not submit comments by email. CDC does not accept acomments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket No. CDC–2021–0003 for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket Access: For access to the docket to read background documents or comments received, or to download an electronic version of the draft policy statement, go to *http://www.regulations.gov.* Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and

Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION:

A. Legal Authority

HHS/CDC is promulgating this policy under the authority of sections 201–204 and 221 of Title II of Public Law 107–188, 116 Stat 637 (42 U.S.C. 262a).

B. Background

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) (42 U.S.C. 262a(a)(1)), the HHS Secretary regulates a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The biological agents and toxins listed in 42 CFR 73.3 (HHS select agents and toxins) have the potential to pose a severe threat to human health and safety and are regulated only by HHS/CDC. The biological agents listed in § 73.4 (overlap select agents and toxins) have not only the potential to pose a severe threat to human health and safety; but have been determined by the USDA, pursuant to USDA's authority under the Agriculture Bioterrorism Protection Act of 2002 (7 U.S.C. 8401), to have the potential to pose a severe threat to animals and animal products. Accordingly, these biological agents are jointly regulated by HHS/CDC and USDA as ''overlap'' select agents. The Bioterrorism Response Act defines the term ''overlap agent or toxin'' to mean a biological agent or toxin that is listed pursuant to 42 U.S.C. 262a and is listed pursuant to 7 U.S.C. 8401. See 7 U.S.C. 8411.

Brucellosis, also known as contagious abortion or Bang's disease, is a contagious, costly disease that has significant animal health, public health, and international trade consequences. While most often found in ruminant animals (*e.g.,* cattle, bison, cervids and swine), brucellosis can affect other animals and is transmissible to humans. Brucellosis is caused by a group of bacteria known scientifically as the genus *Brucella.* Two species of *Brucella* found in the United States: *B. abortus,* principally affecting cattle, bison, and cervids, and *B. suis,* principally affecting swine and reindeer, but also cattle and bison.

Brucellosis can be costly to agriculture production. In 1952, prior to established efforts to eradicate the disease, agriculture production losses due to brucellosis exceeded $400 million. A cautionary indicator of the need for greater understanding of the disease is the expanding range of endemic *B. abortus* in the Greater Yellowstone Area and *B. suis* in feral swine populations throughout various areas of the United States. This disease expansion emphasizes the critical need for improved diagnostics, along with vaccine development for both *Brucella* species, which could be furthered by outdoor research studies.

Both *B. abortus* and *B. suis* are currently listed as overlap select agents in select agent regulations (42 CFR 73.4 and 9 CFR 121.4). Accordingly, any outdoor research studies must comport with the select agent and toxin regulations. Therefore, HHS/CDC and USDA are issuing a FSAP draft policy statement on biosafety for large animal outdoor containment studies with *B. abortus* and *B. suis* to aid individuals and entities in the development of biosafety plans for such studies that meet the requirements of the select agent regulations. We are making this policy document available to the public at the Supporting & Related Materials tab of the docket and at *https://www.selectagents.gov/regulations/policy/animalstudy.htm* for review and comment.

Copies of the policy document are also available for public inspection at USDA, room 1620, South Building, 14th Street and Independence Avenue SW, Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021–00877 Filed 1–14–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0002]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on January 27, 2021 from 10:00 a.m. to 5:00 p.m., EST (times subject to change, see the ACIP website for any updates: *http://www.cdc.gov/vaccines/acip/index.html*).

Written comments must be received on or before January 27, 2021.

ADDRESSES: For more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

You may submit comments, identified by Docket No. CDC–2021–0002 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket No. CDC–2021–0002, c/o Attn: January 27, 2021 ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329–4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

Written public comments submitted 24 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency.

Purpose: The committee is charged with advising the Director, CDC, on the