IRB shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor potentially participating in the research on a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should: (1) Contain an explanation of the study; (2) a description of what is required of the subject (*e.g.,* what he or she will experience (whether the minor will be in the hospital, whether the minor's parents will be with him or her, etc.)); (3) an explanation of any risks and pain associated with the study; (4) an explanation of any anticipated change in the minor's appearance; and (5) an explanation of the benefits to the minor or others.

FDA plans to use the data collected under the generic clearance to inform the following information for education, interventions, outcomes, regulatory science programs, materials and resources, and disease prevention and treatment. FDA expects the data to guide the formulation of the Agency's educational and public health objectives on FDA-regulated products and support development of subsequent research efforts. The data will not be used to make policy or regulatory decisions. Rather, these data will: (1) Inform FDA's public education campaigns and other educational/interventional materials directed to informing consumers, patients, caregivers, and public health professionals about human and animal health issues; and (2) provide information on the safety, efficacy, and usage of FDA-regulated products.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB, along with supporting documentation (*e.g.,* a copy of the interview or moderator guide, screening questionnaire).

FDA will submit individual qualitative and quantitative collections under this generic clearance to the OMB. Individual collections will also undergo review by FDA's IRB, senior leadership for the primary investigator's respective offices, and PRA specialists.

Description of Respondents: The respondents to this collection of information are all FDA stakeholders, including general population individuals, as well as consumers of certain products, patients and their caregivers, academic/scientific experts, individuals from specific target labor groups, such as physicians, medical specialists, pharmacists, dentists, nurses, veterinarians, dietitians, and other public health professionals.

In the **Federal Register** of July 7, 2020 (85 FR 40655), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although five comments were received, they were not responsive to the four collection of information topics solicited and, therefore, will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys/Focus Groups	2,520	14.6	36,792	0.25 (15 minutes)	9,198

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a new collection of information whose total estimated annual reporting burden is 9,198 hours. The number of participants to be included in each individual generic submission under this collection of information will vary, depending on the nature of the compliance efforts and the target audience.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04407 Filed 3–2–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 Board of Scientific Counselors, NIAMS.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAMS.

Date: April 27–28, 2021.

Time: April 27, 2021, 12:30 p.m. to 4:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Time: April 28, 2021, 12:00 p.m. to 4:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John J. O'Shea, MD, Ph.D., Scientific Director, National Institute of Arthritis & Musculoskeletal and Skin Diseases, Building 10, Room 6N204, Bethesda, MD 20892, (301) 496–2612, *osheajo@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: _February 25, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–04366 Filed 3–2–21; 8:45 am]

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