

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Study 1 (Survey) Cognitive interview screener	75	1	75	0.083 (5 minutes) ..	6
Study 2 (Experiment) Cognitive interview screener ² ..	75	1	75	0.083 (5 minutes) ..	6
Study 1 (Survey) Cognitive interview	5	1	5	1	5
Study 2 (Experiment) Cognitive interview	9	1	9	1	9
Study 1 (Survey) Pretest	60	1	60	0.17 (10 minutes) ...	10
Study 2 (Experiment) Pretest	180	1	180	0.25 (15 minutes) ...	45
Study 1 (Survey)	2,000	1	2,000	0.17 (10 minutes) ..	340
Study 2 (Experiment)	5,000	1	5,000	0.25 (15 minutes) ..	1,250
Total					1,671

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

² Since Study 3 is identical to Study 2, only one set of cognitive interviews and pre-tests are needed.

II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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- Sheff, J.N., 2011. "Biasing Brands." *Cardozo Law Review*, 32(4), pp. 1245–1314.
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- Azjen, I., 2016. "Consumer Attitudes and Behavior: The Theory of Planned Behavior Applied to Food Consumption Decisions." *Italian Review of Agricultural Economics*, 70(2), pp. 121–138.

Dated: March 21, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Organizational Representatives to the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations from organizations to send representatives to be a liaison to the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee). Selections will be based on a review of the organization's subject area of expertise, mission, relevancy, and benefit provided relative to the Committee's purpose. The organizational representatives are non-voting liaisons. The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of HHS.

DATES: Written nominations for organizational representatives to the ACHDNC must be received on or before May 2, 2022.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Soohyun Kim, MPH, CPH, Acting Designated Federal Officer (DFO) at ACHDNC@hrsa.gov.

FOR FURTHER INFORMATION CONTACT:

Acting DFO Soohyun Kim, MPH, CPH; Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18–N–38A, Rockville, MD 20857; 301–594–4202; or ACHDNC@hrsa.gov. A copy of the Committee charter and list of current membership is available on the Committee's website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

SUPPLEMENTARY INFORMATION: ACHDNC

was established in 2003 to provide advice and recommendations to the Secretary on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP), and fulfills requirements stated in the authorizing legislation. ACHDNC's recommendations regarding inclusion of additional conditions/inherited disorders for screening that, when adopted by the Secretary, are included in the RUSP, and constitute part of the evidence-informed comprehensive preventive health services guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and group and individual health insurance issuers are required to provide coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, in the individual market, policy years) beginning on or

after the date that is 1 year from the Secretary's adoption of the condition.

ACHDNC also provides advice and recommendations to the Secretary concerning grants, projects and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having or at risk for heritable disorders.

ACHDNC meets four times each calendar year, or at the discretion of the DFO in consultation with the Chair.

Nominations: The Committee may invite organizations to designate individuals to serve as non-voting liaisons. Organizations should demonstrate wide-ranging newborn screening and heritable disorders interests. In addition, the organization's work should inform the activities of the Committee. Eligible organizations must represent national public health constituencies, medical professional societies, or organizations with large, broad constituencies and broad interest or involvement in newborn screening. Organizations that represent narrow interests (e.g., interest in a single disease treatment) or smaller constituencies are not eligible. Organizational representatives attend Committee meetings to provide relevant expertise and perspectives to Committee members during their deliberations and discussions, but they do not vote and are not official members of the Committee.

Applications must contain a cover letter and statement. The cover letter should include the organization name and mission statement; contact information for the designated representative, including point of contact name, address, email, telephone number; and website of the organization. The statement should include the perspective and expertise provided by the organization and its relevance to the Committee; description of how the Committee's work affects and impacts the organization and its constituency; a list of organizational projects, programs, and products that are of relevance to the Committee's work; an affirmation of the organization's commitment to identify a representative with expertise who can attend Committee meetings in person (when applicable) and provide input to the Committee at the discretion of the Chair; an affirmation of the organization's commitment to financially support (e.g., cover travel expenses) a representative to attend any in-person Committee meetings held in

Rockville, Maryland; an affirmation of the organization's commitment to ensure active contribution to and dissemination of Committee activities and recommendations to its constituencies; affirmation the designated representative is able to serve as the liaison; and an affirmation that the organization has no conflict of interest that would preclude informing the Committee in a fair and balanced manner. If there are potential conflicts of interest, please detail the information concerning any potential conflicts of interest relative to both the organization and the proposed organizational representative (e.g., current or anticipated employment, consultancies, research grants, or contracts), as well as how the organization proposes to address the potential conflict.

Organizations are eligible to send a representative as long as the organization's subject area of expertise and mission is relevant to the Committee's purpose, objective, scope of activities and duties, and as long as the organization actively participates in Committee activities. Every 3 years, the Chair and DFO will re-assess the organization's mission, relevancy, and benefit as it relates to the Committee's purpose, objective, scope of activities and duties. Every 3 years, current organizations will be asked to reaffirm their commitment to support an organizational representative.

The selection of eligible organizations is based on a review of the organization's subject area of expertise, mission, relevancy, and benefit as it relates to the Committee's purpose.

Authority: Section 1111(g) of the Public Health Service Act, 42 U.S.C. 300b-10(g), Section 222 of the Public Health Service Act, 42 U.S.C. 217a, and the Federal Advisory Committee Act, 5 U.S.C. App.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee). ACHDNC provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of HHS (Secretary). HRSA is seeking nominations of qualified candidates for appointment to two positions on the Committee beginning in 2023, each serving a term of up-to 4 years.

DATES: Written nominations for membership on the Committee must be received on or before April 11, 2022.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Soohyun Kim, MPH, CPH, Acting Designated Federal Officer (DFO) at ACHDNC@hrsa.gov.

FOR FURTHER INFORMATION CONTACT:

Acting DFO Soohyun Kim, MPH, CPH; Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18-N-38A, Rockville, MD 20857; 301-594-4202; or ACHDNC@hrsa.gov. A copy of the Committee charter and list of the current membership is available on the Committee's website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/about/index.html>.

SUPPLEMENTARY INFORMATION: ACHDNC was established in 2003 to provide advice and recommendations to the Secretary on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP), and fulfills requirements stated in the authorizing legislation. ACHDNC's recommendations regarding inclusion of additional conditions/inherited disorders for screening that, when adopted by the Secretary, are included in the RUSP, and constitute part of the evidence-informed comprehensive preventive health services guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and group and individual