

II. Paperwork Reduction Act of 1995

While this guidance contains no 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 collection of information for current good manufacturing practice requirements has been approved under OMB control number 0910–0139. The collections of information for adverse event reporting and human drug compounding under sections 503A and 503B (21 U.S.C. 353a and 353b) of the FD&C Act have been approved under OMB control number 0910–0800. The collections of information for adverse event and product experience reporting under the MedWatch System has been approved under OMB control number 0910–0291.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: February 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03158 Filed 2–10–23; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

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

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute

with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.” Set forth below is a list of petitions received by HRSA on December 1, 2022, through December 31, 2022. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city

and state of the person or attorney filing the claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and

2. Any allegation in a petition that the petitioner either:

a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or

b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading “For Further Information Contact”), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court’s caption (Petitioner’s Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Carole Johnson,

Administrator.

List of Petitions Filed

1. Abdulaziz Alanazi, Martin, Tennessee, Court of Federal Claims No: 22–1753V
2. Justin Hargett, Baltimore, Maryland, Court of Federal Claims No: 22–1755V
3. Russell Probst, Covington, Louisiana, Court of Federal Claims No: 22–1757V

4. Karen Dodge, San Rafael, California, Court of Federal Claims No: 22–1759V
5. William Walkerm, Selmer, Tennessee, Court of Federal Claims No: 22–1762V
6. Suzanne Brogan, Cicero, New York, Court of Federal Claims No: 22–1768V
7. Rebecca Lake Pool, Orlando, Florida, Court of Federal Claims No: 22–1771V
8. Jennifer Noone, Union, New Jersey, Court of Federal Claims No: 22–1772V
9. Lorraine E. Ginz, Peoria, Illinois, Court of Federal Claims No: 22–1773V
10. Lee Apfel, La Crosse, Wisconsin, Court of Federal Claims No: 22–1774V
11. Julie McLaughlin, North Charleston, South Carolina, Court of Federal Claims No: 22–1776V
12. Kathleen Knouse, Aventura, Florida, Court of Federal Claims No: 22–1777V
13. Philip Weseman, St. Louis, Missouri, Court of Federal Claims No: 22–1780V
14. Nicole Jemison, Discovery Bay, California, Court of Federal Claims No: 22–1781V
15. Lorraine E. Ginz, Peoria, Illinois, Court of Federal Claims No: 22–1783V
16. Melissa Mello, Randolph, Massachusetts, Court of Federal Claims No: 22–1784V
17. Daniel Janosik on behalf of the Estate of Elva Janosik, Deceased, Boston, Maryland, Court of Federal Claims No: 22–1785V
18. Gwendolyn Kieft, Phoenix, Arizona, Court of Federal Claims No: 22–1787V
19. Laurence Chitlik, Cambridge, Maryland, Court of Federal Claims No: 22–1790V
20. April York on behalf of A. Y., Phoenix, Arizona, Court of Federal Claims No: 22–1796V
21. Deborah Helldoerfer, Hilliard, Ohio, Court of Federal Claims No: 22–1798V
22. Brittany Moran Ogilvie on behalf of A. O., Chicago, Illinois, Court of Federal Claims No: 22–1799V
23. Dennis A. Kopolovich, Monroeville, Pennsylvania, Court of Federal Claims No: 22–1805V
24. Mary G. Dowd, Bridgewater, Massachusetts, Court of Federal Claims No: 22–1806V
25. Daizhanea Gaines, Baltimore, Maryland, Court of Federal Claims No: 22–1808V
26. Patrick B. Highland, Raleigh, North Carolina, Court of Federal Claims No: 22–1809V
27. Theresa Grillo, Deerfield Beach, Florida, Court of Federal Claims No: 22–1810V
28. Jessica Kennedy, Westerville, Ohio, Court of Federal Claims No: 22–1812V
29. Angela Risner, Waukee, Iowa, Court of Federal Claims No: 22–1813V
30. Margaret Schellhaas, Conneaut Lake, Pennsylvania, Court of Federal Claims No: 22–1819V
31. Sheela Taylor, Raleigh, North Carolina, Court of Federal Claims No: 22–1820V
32. Jeanie Dehart-Manzo, Hood River, Oregon, Court of Federal Claims No: 22–1822V
33. Deborah Carpenter, Washington, District of Columbia, Court of Federal Claims No: 22–1823V
34. Sandra L. Abbott, Baltimore, Maryland, Court of Federal Claims No: 22–1824V
35. Kevin C. McCarthy, Denver, Colorado, Court of Federal Claims No: 22–1825V
36. Marla Kay Sommerfield, Rochester, Minnesota, Court of Federal Claims No: 22–1830V
37. Paul Braun, Jr., Pennsburg, Pennsylvania, Court of Federal Claims No: 22–1831V
38. Michelle Eubanks on behalf of K. L., Phoenix, Arizona, Court of Federal Claims No: 22–1832V
39. Elizabeth Miller, Phoenix, Arizona, Court of Federal Claims No: 22–1833V
40. Heather Nattkemper, Ashburn, Virginia, Court of Federal Claims No: 22–1838V
41. Vivian Oliver, New York, New York, Court of Federal Claims No: 22–1852V
42. Cindy O'Connor, Williamsport, Pennsylvania, Court of Federal Claims No: 22–1853V
43. Youn Hee Lee, Phoenix, Arizona, Court of Federal Claims No: 22–1855V
44. Tiffany Hudson, Phoenix, Arizona, Court of Federal Claims No: 22–1856V
45. Kelli O'Connell, Lawrenceville, Georgia, Court of Federal Claims No: 22–1859V
46. Keith Pillischafske, Champaign, Illinois, Court of Federal Claims No: 22–1860V
47. Bennett C. Meltzer, Orange, California, Court of Federal Claims No: 22–1861V
48. Alyssa Robinson, Phoenix, Arizona, Court of Federal Claims No: 22–1862V
49. Jessica Brown, Phoenix, Arizona, Court of Federal Claims No: 22–1863V
50. Stella Cook, Bryan, Texas, Court of Federal Claims No: 22–1864V
51. Rebecca Pick, Phoenix, Arizona, Court of Federal Claims No: 22–1866V
52. Kathryn Kirchner, Grand Haven, Michigan, Court of Federal Claims No: 22–1867V
53. Kaitlyn Wilson, Phoenix, Arizona, Court of Federal Claims No: 22–1876V
54. Denise Heinle on behalf of the Estate of Virgil Heinle, Deceased, St. Louis, Missouri, Court of Federal Claims No: 22–1877V
55. Dawn A. McNair, Fayetteville, North Carolina, Court of Federal Claims No: 22–1878V
56. Sean F. Rowell, II, New Lisbon, Wisconsin, Court of Federal Claims No: 22–1879V
57. Michelle Bridges, Marion, Indiana, Court of Federal Claims No: 22–1881V
58. Melissa Ballard on behalf of Estate of Kenneth Wayne Ballard, Deceased, Henderson, Nevada, Court of Federal Claims No: 22–1884V
59. George Ling, Greensboro, North Carolina, Court of Federal Claims No: 22–1886V
60. Beatriz Bowman, Arlington, Texas, Court of Federal Claims No: 22–1889V
61. Janmarie Mazzone, San Jose, California, Court of Federal Claims No: 22–1891V
62. Tiffany Brooks, Queens, New York, Court of Federal Claims No: 22–1892V
63. Rachel Magoon, Vancouver, Washington, Court of Federal Claims No: 22–1893V
64. James Stanfield, Surprise, Arizona, Court of Federal Claims No: 22–1894V
65. Stephanie Cox, Raleigh, North Carolina, Court of Federal Claims No: 22–1895V
66. James M. Helm, Aventura, Florida, Court of Federal Claims No: 22–1896V
67. Khadijah Hasan on behalf of A. S., Aventura, California, Court of Federal Claims No: 22–1897V
68. Elizabeth Cameron, Aurora, Colorado, Court of Federal Claims No: 22–1898V
69. Mitchell Foster, Boston, Massachusetts, Court of Federal Claims No: 22–1899V
70. Betty Farmer, Marshall, Michigan, Court of Federal Claims No: 22–1900V
71. Kenyondra Langford on behalf of J. S., Phoenix, Arizona, Court of Federal Claims No: 22–1901V
72. Jessica Richardson, Greenville, North Carolina, Court of Federal Claims No: 22–1902V

73. Lauralee Miller, Murray, Utah, Court of Federal Claims No: 22–1903V
74. Ciena Westrich, Phoenix, Arizona, Court of Federal Claims No: 22–1906V
75. Randy Ritchie, Savannah, Georgia, Court of Federal Claims No: 22–1907V
76. Lisa Snell on behalf of K. W., Phoenix, Arizona, Court of Federal Claims No: 22–1909V
77. Suzanne Meeley, Drexel Hill, Pennsylvania, Court of Federal Claims No: 22–1911V
78. Gonzalo Lopez and Rosalia Lopez on behalf of A. L., Phoenix, Arizona, Court of Federal Claims No: 22–1912V
79. Chelsea Hughes, Olney, Maryland, Court of Federal Claims No: 22–1917V
80. Tiffany Taylor on behalf of C. T., Stanford, Kentucky, Court of Federal Claims No: 22–1918V
81. Aidan Walsh, Boston, Massachusetts, Court of Federal Claims No: 22–1919V
82. Aubrielle Smythe, Huntsville, Alabama, Court of Federal Claims No: 22–1920V
83. Sakinah Wood, Atlanta, Georgia, Court of Federal Claims No: 22–1924V
84. Alexander Kurk, St. Petersburg, Florida, Court of Federal Claims No: 22–1930V
85. Joseph Pilcher, Los Angeles, California, Court of Federal Claims No: 22–1931V
86. John D. Sherwood, Lexington, Ohio, Court of Federal Claims No: 22–1934V
87. Lorraine Martin, Port Orange, Florida, Court of Federal Claims No: 22–1936V
88. Lorraine Martin, Port Orange, Florida, Court of Federal Claims No: 22–1937V
89. Anwesa Paul, Westfield, New Jersey, Court of Federal Claims No: 22–1938V
90. Danielle Spiller, Manalapan, New Jersey, Court of Federal Claims No: 22–1939V
91. Elizabeth Cimino, Phoenix, Arizona, Court of Federal Claims No: 22–1940V
92. Prisca Thomas, Beverly Hills, California, Court of Federal Claims No: 22–1941V

[FR Doc. 2023–03184 Filed 2–14–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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. 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 General Medical Sciences Special Emphasis Panel; Renewal of Centers of Biomedical Research Excellence (COBRE) (Phase 2).

Date: March 2–3, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN18–01, Bethesda, Maryland 20892, 301–594–3663, sidorova@nigms.nih.gov.

Information is also available on the Institute's/Center's home page: www.nigms.nih.gov/, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: February 9, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–03174 Filed 2–14–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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. 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; George M. O'Brien Kidney Consortium Review.

Date: March 29–31, 2023.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301–594–2242, jerkinsa@nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 9, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–03175 Filed 2–14–23; 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 10(d) of the Federal Advisory Committee Act, as