

event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

**Comments:** FDA is holding this public workshop to obtain feedback from the community on the questions in the discussion paper. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is March 20, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **Comments**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

## I. Background

In vitro diagnostic devices, including laboratory-developed tests that utilize

NGS technology to generate information on an individual's genome, are rapidly transforming healthcare. Because NGS tests generate large amounts of data and consequently may have relatively broad or undefined intended uses or indications, these tests pose certain challenges during review of premarket submissions. At the same time, this large amount of data provides opportunities for novel approaches to assure the analytical and clinical validity of NGS tests. FDA is committed to providing efficient and effective oversight for NGS tests to assure their safety and effectiveness. By doing so, FDA will promote innovation and advance precision medicine. The Agency is therefore requesting public input on the regulatory strategy for NGS tests that produce results on variation in the human genome. Further details of current and new approaches that may be considered in the workshop are outlined in the discussion paper entitled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests" available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

## II. Topics for Discussion at the Public Workshop

The workshop discussion will focus on regulatory strategies to assure the analytical and clinical validity of NGS tests. Specific topics to be discussed at the workshop are outlined in the discussion paper entitled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests" available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list). A detailed agenda will be posted on this Web site in advance of the workshop.

Dated: December 22, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014-30308 Filed 12-22-14; 4:15 pm]

**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, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services 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 the Clerk, 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 11C-26, Rockville, MD 20857; (301) 443-6593.

**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 U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, 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 Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which 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 November 1, 2014, through November 30, 2014. This list provides the name of petitioner, city, and state of vaccination (if unknown then city and state of person or attorney filing 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) “Sustained, 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) “Sustained, 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 U.S. 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, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857. The Court’s caption (Petitioner’s Name v. Secretary of Health and Human Services) 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.

Dated: December 17, 2014.

**Mary K. Wakefield,**

*Administrator.*

#### List of Petitions Filed

1. Candi Gonzalez on behalf of Marley Alecia-Sapphire Morales, Linwood, New Jersey, Court of Federal Claims No: 14-1072V.
2. Rosemary West, Walnut Creek, California, Court of Federal Claims No: 14-1073V.
3. Michael Smith, Kalispell, Montana, Court of Federal Claims No: 14-1074V.
4. Karen Comeiro, Boston, Massachusetts, Court of Federal Claims No: 14-1075V.
5. Louis Mansolillo, Providence, Rhode Island, Court of Federal Claims No: 14-1080V.
6. Donald Weiss, Rossford, Ohio, Court of Federal Claims No: 14-1081V.
7. Lynn Henderson, Lafayette, Indiana, Court of Federal Claims No: 14-1082V.
8. Marilyn Witbrodt, Palm Harbor, Florida, Court of Federal Claims No: 14-1086V.
9. Martha Scrantom, Hillsborough, North Carolina, Court of Federal Claims No: 14-1087V.
10. Stephanie Stout on behalf of Z. S., Louisville, Kentucky, Court of Federal Claims No: 14-1088V.
11. Howard McCosh, Provo, Utah, Court of Federal Claims No: 14-1089V.
12. Virgil Kim, Bothell, Washington, Court of Federal Claims No: 14-1090V.
13. Natalee Hessell, Troy, Michigan, Court of Federal Claims No: 14-1091V.
14. Jasmine Morgan on behalf of C. S., Deceased, Roanoke, Virginia, Court of Federal Claims No: 14-1094V.
15. Kristen Walter, Mt. Holly, New Jersey, Court of Federal Claims No: 14-1095V.
16. Milford B. Reiman, Wellesley Hills, Massachusetts, Court of Federal Claims No: 14-1096V.
17. Janice Steinkamp, Lincoln, Nebraska, Court of Federal Claims No: 14-1097V.
18. Jeffrey Edgar, Marblehead, Massachusetts, Court of Federal Claims No: 14-1098V.
19. Nicholas J. Xanthopoulos, St. Paul, Minnesota, Court of Federal Claims No: 14-1101V.
20. Kayla Nichols and Jason Nichols on behalf of Noah Nichols, Phoenix, Arizona, Court of Federal Claims No: 14-1103V.
21. Kristina Ries on behalf of Nickolas Ries, Deceased, Phoenix, Arizona, Court of Federal Claims No: 14-1104V.
22. Noemi Frette on behalf of N. F., Scottsdale, Arizona, Court of Federal Claims No: 14-1105V.
23. Kathi Aho, St. Cloud, Minnesota, Court of Federal Claims No: 14-1106V.
24. Matthew Smith and Michelle Smith on behalf of M. S., Chicago, Illinois, Court of Federal Claims No: 14-1107V.
25. Suzanne Fuhri on behalf of Thomas Fic, Chicago, Illinois, Court of Federal Claims No: 14-1108V.
26. Purvi Desai-Leyva, Albany, New York, Court of Federal Claims No: 14-1109V.
27. Olga Molina, San Antonio, Texas, Court of Federal Claims No: 14-1110V.
28. Eula Jane Matthews, Cleburne, Texas, Court of Federal Claims No: 14-1111V.
29. Ashley Puroll on behalf of P. H., Muskegon, Michigan, Court of Federal Claims No: 14-1112V.
30. Paul Judge, Glen Rock, New Jersey, Court of Federal Claims No: 14-1113V.
31. Antoinette McCormick, College Station, Texas, Court of Federal Claims No: 14-1114V.
32. Daniel E. McKinney, Berkeley Heights, New Jersey, Court of Federal Claims No: 14-1116V.
33. Robin McCarthy-Stancavage on behalf of A. S., Severna Park, Maryland, Court of Federal Claims No: 14-1117V.
34. Cornell Yellen, Souderton, Pennsylvania, Court of Federal Claims No: 14-1118V.
35. Eva Cruz and Omar Lopez Jimenez on behalf of L. J. L., Deceased, Las Vegas, Nevada, Court of Federal Claims No: 14-1119V.
36. Elmer D. McKercher, Duluth, Minnesota, Court of Federal Claims No: 14-1124V.
37. Barbara Goforth, Farmville, Virginia, Court of Federal Claims No: 14-1128V.
38. Teresa Bray, Green Bay, Wisconsin, Court of Federal Claims No: 14-1131V.
39. Judith Rosenfield, Sherman Oaks, California, Court of Federal Claims No: 14-1132V.
40. Jose Guadalupe Garcia, II, Pasadena, Texas, Court of Federal Claims No: 14-1136V.
41. Robert Handeyside, Saginaw, Michigan, Court of Federal Claims No: 14-1137V.

42. Marlie Dulaurier, M.D., Columbus, Ohio, Court of Federal Claims No: 14–1138V.
43. Larry Thompson, Lynchburg, Virginia, Court of Federal Claims No: 14–1139V.
44. Richard Greenslade, Ann Arbor, Michigan, Court of Federal Claims No: 14–1140V.
45. Navid Nourani, Tempe, Arizona, Court of Federal Claims No: 14–1142V.
46. Andrew Funk, Tempe, Arizona, Court of Federal Claims No: 14–1143V.
47. Duke Duquette, Uxbridge, Massachusetts, Court of Federal Claims No: 14–1144V.
48. Candace Johnson, Portland, Oregon, Court of Federal Claims No: 14–1145V.
49. Thalia Monsha Stallworth Lewis on behalf of Alton Jerome Lewis, Deceased, Birmingham, Alabama, Court of Federal Claims No: 14–1147V.
50. Billy Whitchurch, Dallas, Texas, Court of Federal Claims No: 14–1148V.
51. Andrea Gasaway, Dallas, Tennessee, Court of Federal Claims No: 14–1149V.
52. Barbara Budgake, Rahway, New Jersey, Court of Federal Claims No: 14–1150V.
53. Douglas A. Dinunzio, Charlotte, North Carolina, Court of Federal Claims No: 14–1151V.
54. Imogene B. Fowler, Tuscaloosa, Alabama, Court of Federal Claims No: 14–1152V.
55. Mary Daniels, Boston, Massachusetts, Court of Federal Claims No: 14–1153V.
56. Amy Junker, Frederick, Maryland, Court of Federal Claims No: 14–1155V.
57. Paula Pasquinelli, Carnegie, Pennsylvania, Court of Federal Claims No: 14–1156V.

[FR Doc. 2014–30402 Filed 12–24–14; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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:* Cell Biology Integrated Review Group; Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

*Date:* January 29–30, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, [balasundaram@csr.nih.gov](mailto:balasundaram@csr.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Risk and Disease Prevention Study Section.

*Date:* January 29–30, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94102.

*Contact Person:* Stacey FitzSimmons, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 451–9956, [fitzsimmons@csr.nih.gov](mailto:fitzsimmons@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Psychosocial Risk and Disease Prevention.

*Date:* January 29, 2015.

*Time:* 10:30 a.m. to 11:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94102.

*Contact Person:* Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, [prenticekj@mail.nih.gov](mailto:prenticekj@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 13–374 Modeling of Social Behavior.

*Date:* January 29, 2015.

*Time:* 12:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Jacinta Bronte-Tinkew, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 806–0009, [brontetinkewjm@csr.nih.gov](mailto:brontetinkewjm@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 19, 2014.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014–30257 Filed 12–24–14; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Correction for National Institute of Neurological Disorders and Stroke, Interagency Pain Research Coordinating Committee Call for Committee Membership Nominations

The National Institutes of Health (NIH) is correcting a notice previously published in the **Federal Register** on December 15, 2014 (79 FR 74102) and titled “National Institute of Neurological Disorders and Stroke, Interagency Pain Research Coordinating Committee Call for Committee Membership Nominations.” The notice announced that The Department of Health and Human Services (HHS) is seeking nominations for the Interagency Pain Research Coordinating Committee.

NIH is amending the due date for nominations from January 5, 2015, as stated toward the end of the notice, to January 12, 2015. For further information about the meeting, please contact Linda Porter, Ph.D., [porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov).

Dated: December 16, 2014.

**Walter J. Koroshetz,**

*Acting Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.*

[FR Doc. 2014–30387 Filed 12–24–14; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. 35). To request a copy of these