

information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and For Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sarah Glavin, Acting Director, Office of Science Policy, Analysis, and Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Dr., Bldg. 31, Rm. 2A28, Bethesda, MD 20892, or call non-toll-free number (301) 496-7898, or email your request, including your address to: [glavins@mail.nih.gov](mailto:glavins@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if

received within 60 days of the date of this publication.

*Proposed Collection:* Application for Consideration for the Media-Smart Youth Leaders Program (A Local Health Education Program and Leadership Opportunity): 0925—New, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

*Need and Use of Information Collection:* Media-Smart Youth: Eat, Think, and Be Active!® is an interactive program designed to teach youth ages 11–13 about how media can affect their health. Developed by the NIH’s Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the program includes 10 lessons on media analysis, nutrition, and physical activity, plus a final capstone project. The Media-Smart Youth® Leaders Program is designed for teens and adults, ages 15 years and up, who are interested in bringing the Media-Smart Youth program to their community. In return for recruiting youth participants, teaching the 10

lessons, and leading the final project, Media-Smart Youth Leaders will receive leadership experience, community service hours, and recognition from the NICHD. To help Leaders succeed, the NICHD will provide training, ongoing assistance, and a small funding amount for program expenses.

The purpose of this information collection is to solicit information from applicants about their qualifications that would make them effective Leaders, their reason for wanting to pursue this opportunity, and the details of their proposed program (including, but not limited to, location, community partner(s), and proposed budget). This information will help NICHD staff select the candidates for the program who are most likely to succeed in implementing the full curriculum and teaching youth effective lessons about nutrition, physical activity, and media.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 800.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Media-Smart Youth Leaders Program Application Form.	Applicants .....	300	1	2.5	750
Media-Smart Youth Leaders Program Application Form.	Advisors .....	300	1	5/60	25
Media-Smart Youth Leaders Program Application Form.	Community partners	300	1	5/60	25

Dated: October 10, 2015.

**Sarah Glavin,**

*Project Clearance Liaison, NICHD, NIH.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

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

**SUMMARY:** The Department of Health and Human Services (HHS) (Department) has created the Interagency Pain Research Coordinating Committee and is seeking nominations for this committee.

**DATES:** Nominations are due by 5 p.m. on November 19, 2015.

**ADDRESSES:** Nominations must be submitted through the web form on the IPRCC Web site: <http://iprcc.nih.gov/about/IPRCC-Nomination.htm>.

**FOR FURTHER INFORMATION CONTACT:** Linda Porter, [porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov).

**SUPPLEMENTARY INFORMATION:** As specified in Public Law 111-148 (“Patient Protection and Affordable Care Act”) the Committee will: (a) Develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain; (b) identify critical gaps in basic and clinical research on the symptoms and causes of pain; (c) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(d) make recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

Membership on the committee will include six (6) non-Federal members from among scientists, physicians, and other health professionals and six (6) non-Federal members of the general public who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. Members will serve overlapping three year terms. It is anticipated that the committee will meet at least once a year.

The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee’s function. Every effort is made to ensure that the views of diverse ethnic and racial groups and

people with disabilities are represented on HHS Federal advisory committees, and the Department therefore, encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Department is soliciting nominations for two non-federal members from among scientists, physicians, and other health professionals and for one non-federal member of the general public who is a representative of a leading research, advocacy, or service organization for people with pain-related conditions. These candidates will be considered to fill positions opened through completion of current member terms. Nominations are due by 5 p.m. on November 19, 2015, using the IPRCC nomination web form: <http://iprcc.nih.gov/about/IPRCC-Nomination.htm>.

Dated: October 8, 2015.

**Walter J. Koroshetz,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

**AGENCY:** National Institutes of Health (NIH), HHS.

**ACTION:** Notice of proposed changes to the *NIH Guidelines*.

**SUMMARY:** The NIH seeks public comment on its proposal to amend the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to incorporate the recommendations of the Institute of Medicine (IOM) regarding human gene transfer clinical research protocols. The NIH proposes amendments to the following: (A) The criteria for selecting protocols for in-depth review and public discussion by the NIH Recombinant DNA Advisory Committee (RAC), (B) the process by which human gene transfer protocols

are reviewed and registered with the NIH, and (C) the streamlining of the NIH protocol registration submission requirements under Appendix M-I-A of the *NIH Guidelines*.

**DATES:** To ensure consideration, comments must be submitted in writing by November 30, 2015.

**ADDRESSES:** Comments may be submitted by email at [OBA-osp@od.nih.gov](mailto:OBA-osp@od.nih.gov), by fax at 301-496-9839, or by mail to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985. All written comments received in response to this notice will be available for public inspection at the NIH Office of Science Policy (OSP), 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted to the NIH OSP Web site.

**FOR FURTHER INFORMATION CONTACT:** If you have questions, or require additional background information about these proposed changes, please contact the NIH by email at [OBA-osp@od.nih.gov](mailto:OBA-osp@od.nih.gov), or telephone at 301-496-9838.

**SUPPLEMENTARY INFORMATION:** The NIH Office of the Director requested that the IOM review whether gene transfer research raises issues of concern that warrant the current level of RAC oversight of individual clinical trials involving gene transfer techniques. The IOM noted that the RAC has served a valuable role, but concluded that the current level of oversight over individual clinical trials is no longer justifiable. In an effort to maximize the benefits of the RAC review process, the IOM recommended that the NIH maintain its protocol submission and safety reporting requirements, but restrict individual gene transfer protocol reviews to exceptional cases that meet specified criteria (full recommendations are listed in the IOM report *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee* (<http://www.iom.edu/Reports/2013/Oversight-and-Review-of-Clinical-Gen-Transfer-Protocols.aspx>)).

After careful consideration of the IOM's recommendations, the NIH proposes amendments to the *NIH Guidelines* in the following areas:

A. *Criteria and process for selecting protocols for RAC review.* The following criteria (subsequently referred to as the NIH RAC review criteria) are proposed for initiating RAC review of individual human gene transfer protocols (criteria listed in both items 1 and 2 must be met):

1. An oversight body (an Institutional Biosafety Committee (IBC) or an Institutional Review Board (IRB)) determines that a human gene transfer protocol submitted to it for approval would significantly benefit from RAC review; and

2. One or more of the criteria below are satisfied:

a. The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk.

b. The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value.

c. The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously.

The chair of an oversight body or an authorized oversight body representative may submit a request for RAC review by sending the request to the NIH as part of the submission materials provided by the PI. This request must include the rationale for why the protocol satisfies both items 1 and 2 of the NIH RAC review criteria. The NIH will review the request and notify the requestor of a decision in no more than ten working days.

1. If the NIH determines that the criteria listed in both 1 and 2 above are satisfied, the NIH Director will convene the RAC.

2. If the NIH receives a request for RAC review of a protocol that the NIH determines does not meet both of these criteria, the NIH would:

a. Inform the requestor that RAC review is not warranted, and

b. offer to provide the requestor with information about previous protocols that have used similar products, the outcome of those studies, if available, and a summary of relevant safety data.

3. Even if the protocol does not meet the proposed criteria listed in both items 1 and 2 above, the NIH Director, in consultation (if necessary) with appropriate regulatory authorities (e.g., the Office for Human Research Protections, the Food and Drug Administration), can select protocols for review that may present significant scientific, societal, or ethical concerns.

B. *Process by which human gene transfer protocols are registered with the NIH.* All human gene transfer protocols subject to Section III-C of the *NIH Guidelines* will continue to be registered with the NIH. However, the following changes are being proposed: