DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting via WebEx is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force) with the HHS Centers for Medicaid & Medicare Services. This meeting will be open to the public via phone.

DATES: The Task Force meeting will be held on Wednesday, June 12, 2019 from 5 p.m. to 6:30 p.m. Eastern Time. The agenda will be posted on the Task Force website at https://www.hhs.gov/ash/advisory-committees/pain/index.html.

ADDRESS: The virtual meeting will be accessible by phone. Information on how to join the meeting will be available on the Task Force website: https://www.hhs.gov/ash/advisory-committees/pain/index.html.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Opportunity To Collaborate on National Youth Sports Initiative To Increase Youth Sports Participation

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of the President’s Council on Sports, Fitness & Nutrition.

ACTION: Notice.

SUMMARY: The Office of the President’s Council on Sports, Fitness & Nutrition (PCSFN) solicits requests from non-Federal public and private sector organizations and entities who wish to collaborate on the National Youth Sports Initiative (NYSI). NYSI collaboration projects will involve executing a singular or series of financially self-sustaining programs, activations, and/or activities that elevate the benefits and importance of youth sports participation and increase sports participation among girls, youth from racial and ethnic backgrounds, and/or youth with a disability. Potential collaborating organizations must have demonstrated interest in and experience with coordinating youth sports-focused activities, be capable of managing the day to day operations associated with the proposed activity, and be willing to participate substantively in the execution of the proposed activity, not just providing funding or logistical support.

DATES: To receive consideration, a request to participate as a collaborating organization must be received via email or postmarked mail at the addresses listed below, by 5:00 p.m. EST on Friday, June 7, 2019. Requests will meet the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Private metered postmarks will not be accepted as proof of timely mailing. Hand-delivered requests must be received by 5:00 p.m. EST on Friday, June 7, 2019. Requests that are received after the deadline will be returned to the sender.

ADDRESSES: Proposals for NYSI collaborations may be submitted via email to Sports@hhs.gov. Proposals may also be sent to Holli Richmond, Executive Director, President’s Council on Sports, Fitness & Nutrition, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Holli Richmond, President’s Council on Sports, Fitness & Nutrition, Office of the Assistant Secretary for Health, HHS; 1101 Wootton Parkway, Suite 560, Rockville, MD 20852; Telephone (240) 276–9866. Email: Sports@hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

PCSFN was established as the President’s Council on Youth Fitness by President Eisenhower in 1956. PCSFN currently operates under Executive Order (E.O.) 13265, amended by E.O. 13824. The Council advises the President, through the Secretary, about progress to expand and encourage youth sports participation, to promote the overall physical fitness, health, and nutrition of all Americans. The Council is the only federal advisory committee focused solely on the promotion of physical activity, fitness, sports, and nutrition.

The Office of the PCSFN works with the President’s Council and, under its authority in Title XVII of the Public Health Service Act, shares the President’s Council’s mission to engage, educate, and empower all Americans to adopt a healthy lifestyle that includes regular physical activity and good nutrition. Through partnerships with the public, private, and non-profit sectors, the Office of the PCSFN
promotes programs and initiatives that motivate people of all ages, backgrounds, and abilities to lead active, healthy lives. The Office of the PCSFN is authorized, in conjunction with its Title XVII authorities, under section 2 of E.O. 13824 to develop a National Youth Sports Initiative (NYSI). Specifically the E.O. states, “The Secretary of Health and Human Services (Secretary), in carrying out the Secretary’s responsibilities for public health and human services, shall develop a national strategy to expand children’s participation in youth sports, encourage regular physical activity, including active play, and promote good nutrition for all Americans.” The purpose of the NYSI is to elevate the importance of youth sports participation, as well as to increase sports participation among youth with below-average sports participation, including girls, youth with a disability or those from racial and ethnic backgrounds; as well as youth in communities with limited access to athletic facilities or recreational areas. The Office of the PCSFN solicits proposals from non-Federal private and public stakeholders who wish to collaborate on the NYSI by planning and executing sport programs, activations, and/or other activities that expand access for and inclusion of youth with below-average sports participation or those from economically distressed areas.

Requirements of the Collaboration

The Office of the PCSFN is seeking organizations capable of managing the development and execution of youth sports programs, activations and/or other activities (such as awareness campaigns), and identifying ways to enhance activities and participation. Approved proposals will require a co-sponsorship signed by both participants and outlined the terms and parameters of the agreement. The co-sponsorship will be in place for a period of one year from the date at which it bears all parties’ signatures.

NYSI Projects

Proposed NYSI projects will develop and implement sport-focused programming, activations, and/or other activities that are evidence-based and result in sustainable strategies that encourage and engage youth in a range of physical activity through sports participation before, during or after the school day. The collaborating organization shall help promote the project through outreach activities that may include using social media, exhibiting at conferences, or speaking at events. The collaborating organization shall identify and recommend ways to enhance delivery and outreach of the youth sports program/activation/activity. Upon signing the above referenced co-sponsorship, and as long as the program/activation/activity meets all requirements, the Office of the PCSFN will grant collaborating organizations the use of its logo and NYSI-branded materials to promote the project, and will highlight the NYSI project via its digital and social media platforms, as deemed appropriate. Use of Office of the PCSFN logo and NYSI-branded materials should not imply any Federal endorsement of the collaborating organization’s general policies, activities, or products.

Eligibility for Collaborating Organizations

To be eligible, a requester shall: (1) Have a demonstrated interest in, understanding of, and experience with managing the development and execution of fun engaging youth sports programs, activations and/or other activities related to promoting the benefits and importance of youth sports participation; (2) participate substantively in the proposed NYSI project (not just provide funding or logistical support); (3) have an organizational or corporate mission that is aligned with the mission of PCSFN and the Department; and (4) agree to sign a co-sponsorship with the Office of the PCSFN which will set forth the details of the NYSI project activity including the requirements that any fees raised should not exceed the collaborating organization’s costs, and fees collected by the collaborating organization shall be limited to the amount necessary to cover the collaborating organization’s related operating expenses. Collaborating organizations are solely responsible for collecting and handling any fees to cover their costs.

The collaborating organization shall furnish the necessary personnel, materials, services, and facilities to administer the proposed NYSI project. These duties will be determined and outlined in a co-sponsorship.

Collaborating Organization Proposal

Each collaborating organization’s proposal shall contain a description of: (1) The entity or organization; (2) its background in managing the development and execution of fun and engaging youth sports programs, activations and/or other activities related to promoting the benefits and importance of youth sports participation; (3) its proposed involvement in the NYSI project; and (4) the proposed project implementation plan with a timeline.

Evaluation criteria: The Office of the PCSFN will select the NYSI projects using the following evaluation criteria:

(1) Requester’s qualifications and capability to fulfill proposed NYSI project responsibilities;

(2) Requester’s creativity in developing and executing the proposed project, including the variety of sport activities offered and the medium through which participants are recruited and project messages are delivered;

(3) Requester’s proposed plan and potential for reaching youth with below-average sports participation or those from economically distressed areas, including girls, youth with a disability, and those from racial and ethnic backgrounds;

(4) Requester’s experience administering national, state and/or local youth sports or physical activity programs, activations and/or activities that have successfully increased youth sports participation or awareness of the benefits and importance of youth sports participation;

(5) Requester’s past or current work specific to programs, activations and/or activities in the area(s) of sports participation among youth with below-average sports participation or those from economically distressed areas;

(6) Requester’s personnel: Name, professional qualifications and specific expertise of key personnel who would be available to work on the NYSI project;

(7) Requester’s facilities and infrastructure: Availability and description of facilities or other infrastructure necessary to develop and execute the programs, activations and/or activities, including sport fields, recreational spaces, office space and information technology and telecommunication resources;

(8) Requester’s description of financial management: Discussion of experience in developing a project budget and collecting and managing monies from organizations and individuals;

(9) Requester’s proposed plan for managing the NYSI project, including such aspects as participant recruitment, website development and/or enhancement, cost of materials, and distribution of those items.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Clinical Trials Reporting Program (CTRP) Database (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Gisele Sarosy, MD, Coordinating Center for Clinical Trials (CCCT), National Cancer Institute, 9609 Medical Center Drive, 6W134, Rockville, MD 20852 or call non-toll-free number 240–276–6172 or Email your request, including your address to: gisele.sarosy@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of 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.

Proposed Collection Title: The Clinical Trials Reporting Program (CTRP) Database, 0925–0600, Expiration Date 08/31/2019—EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) Database is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP website to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually. OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Type of respondents</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average time per response (in hours)</th>
<th>Total annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Registration</td>
<td>Clinical Trials</td>
<td>3,000</td>
<td>1</td>
<td>1</td>
<td>3,000</td>
</tr>
<tr>
<td>Amendment</td>
<td></td>
<td>1,500</td>
<td>4</td>
<td>1</td>
<td>6,000</td>
</tr>
<tr>
<td>Update</td>
<td></td>
<td>1,500</td>
<td>4</td>
<td>1</td>
<td>6,000</td>
</tr>
<tr>
<td>Accrual Updates</td>
<td></td>
<td>3,000</td>
<td>4</td>
<td>15/60</td>
<td>3,000</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>9,000</td>
<td>27,000</td>
<td></td>
<td>18,000</td>
</tr>
</tbody>
</table>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Generic Clearance for Application Information for Fellowships, Internships, Training Programs, and Specialty Positions, National Cancer Institute (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by