DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Extension of Effective Date of NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research


For further information contact the NIH Office of Science Policy.
Telephone: 301–496–9838, Email: SingleIRBPolicy@mail.nih.gov.

Dated: December 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

BILLY COLE 4156-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism.

Date: February 9, 2017.

Closed: 9:00 a.m. to 9:30 a.m.


Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Conference Rooms, Bethesda, MD 20892.

Closed: 9:40 a.m. to 10:50 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Conference Rooms, Bethesda, MD 20892.

Contact Person: Abdurrahman P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, 301–443–9737 bautista@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute’s Center’s home page: http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx, where an agenda and any additional information for the meeting will be posted when available.

TABLE 1—Estimated Annual Reporting Burden1

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric information in an original PMA or PDP—814.20(b)(13)</td>
<td>30</td>
<td>1</td>
<td>30</td>
<td>8</td>
<td>240</td>
</tr>
<tr>
<td>Pediatric information in a PMA amendment—814.37(b)(2)</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>8</td>
<td>80</td>
</tr>
<tr>
<td>Pediatric information in a PMA supplement—814.39(c)(2)</td>
<td>700</td>
<td>1</td>
<td>700</td>
<td>2</td>
<td>1,400</td>
</tr>
<tr>
<td>Pediatric information in an HDE—814.104(b)(6)</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>8</td>
<td>40</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>..........................</strong></td>
<td><strong>..........................</strong></td>
<td><strong>..........................</strong></td>
<td><strong>..........................</strong></td>
<td><strong>1,760</strong></td>
</tr>
</tbody>
</table>

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

Dated: December 12, 2016.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

BILLY COLE 4140-01-P