

- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.

- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.

- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.

- The POD does not maintain continuous oversight of all distribution functions.

- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

These criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect characteristics and yet still be found to be unlawful. Other characteristics not listed above may increase the risk of fraud and abuse associated with a particular POD or provide evidence of unlawful intent. For example, a POD that exclusively serves its physician-owners' patient base poses a higher risk of fraud and abuse than a POD that sells to hospitals and ASCs on the basis of referrals from nonowner physicians.

The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives. Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's

return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

We are aware that some PODs purport to design or manufacture their own devices. OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

IV. Conclusion

OIG is concerned about the proliferation of PODs. This Special Fraud Alert reiterates our longstanding position that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. OIG views PODs as inherently suspect under the anti-kickback statute. Should a POD, or an actual or potential physician-owner, continue to have questions about the structure of a particular POD arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: <http://oig.hhs.gov/faqs/advisory-opinions-faq.asp>.

To report suspected fraud involving physician-owned entities, contact the OIG Hotline at <http://oig.hhs.gov/fraud/report-fraud/index.asp> or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

Dated: March 26, 2013.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2013-07394 Filed 3-28-13; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request: Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on 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.

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 NIDA Program Official: Dr. Steve Gust, National Institute on Drug Abuse, 6001 Executive Blvd., Bethesda, MD 20892, or call non-toll-free number (301) 443-6480 or Email your request, including your address to: sgust@nida.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comments 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: Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device, 0925-New, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will examine the

effectiveness of a mobile scalable device to detect the impairing effects of different drugs. The primary purpose of the data collected is to determine eligibility in a driving simulation study and to verify the effectiveness of the

experimental manipulations. The findings will provide valuable information concerning the utility and effectiveness of mobile, smartphone/tablet-based neurocognitive assessment that can provide a multifactorial

evaluation of cognitive functioning associated with impaired driving.

OMB approval is requested for 18 months. There are no costs to respondents other than their time. The total annualized burden hours are 58.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Per annual hour burden
Phone Screening	Adults	100	1	10/60	17
Driving Survey	Adults	72	1	15/60	18
Realism Survey	Adults	72	1	3/60	4
Sleep and Intake Questionnaire	Adults	72	2	3/60	7
Stanford Sleepiness Scale	Adults	72	6	1/60	7
Wellness Survey	Adults	72	2	2/60	5

Dated: March 25, 2013.

Glenda J. Conroy,

Executive Officer (OM Director), NIDA, NIH.

[FR Doc. 2013-07349 Filed 3-28-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meeting

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 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: Center for Scientific Review Special Emphasis Panel Rheumatology, Dermatology and Osteoclast Biology.

Date: April 30, 2013.

Time: 1:00 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: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, beheraak@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: March 25, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-07288 Filed 3-28-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meeting

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 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.

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Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, beheraak@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: March 25, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-07307 Filed 3-28-13; 8:45 am]

BILLING CODE 4140-01-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.