DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Implementation.

Date: April 8, 2013.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817.

Contact Person: Gregory P. Jarosik, Ph.D., Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–496–0695, *gjarosik@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 11, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–05968 Filed 3–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Multidisciplinary K12 Urological Research Career Development Program.

Date: April 4, 2013.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 11, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–05969 Filed 3–14–13; 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. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 and Opioid Treatment Programs (OTPs) (OMB No. 0930–0206)—Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. ''Certification'' is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168), which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient's medical examination when admitted to treatment, A patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic

attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

There are no changes being made to the forms. The reason for the reduction in burden hours is due to more respondents submitting information through an online function. The forms are available online with a unique feature for both the SMA–162 and SMA–168 that pre-populates certain information within the form. This in turn reduces the program's time spent filling out the forms as well as the staff time spent on processing it. Also, a final rule effective January 7, 2013, (77 FR 72752, **Federal Register** December 6, 2012) eliminated dispensing restrictions for buprenorphine products used in OTPs. As a result there OTPs will complete and submit fewer SMA–168 forms, therefore reducing burden hours.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA–163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status	1	185	185	0.3	55.0
Sub Total		54		1,407		394.20

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(b)	Renewal of approval (SMA–162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA–162)	35	1	35	1.17	40.95
8.11(e)(1)	Application for provisional certification	42	1	42	1	42.00
8.11(e)(2)	Application for extension of provisional certification.	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	60	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA–168).	1,200	20	24,000	0.07	1680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement.	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review.	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement.	2	1	2	5.00	10.00
Sub Total		1,775		24,594		1868.95
Total		1,829		26,001		2,263.15

Written comments and recommendations concerning the proposed information collection should be sent by April 15, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2013–06029 Filed 3–14–13; 8:45 am]

BILLING CODE 4162–20–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. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Evaluation of Emergency Department Crisis Center Follow-Up—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct an evaluation to assess the impact of crisis center follow-up with patients admitted to emergency departments following a suicide attempt.

The overarching purpose of the proposed Evaluation of Emergency Department Crisis Center Follow-up—New is to examine the impact of crisis center follow-up with patients admitted to emergency departments following a suicide attempt on subsequent emergency department readmissions. In total this evaluation effort includes two data collection activities.

Clearance is being requested to abstract patient hospital data and companion crisis center data to examine the impact of crisis center follow-up on readmissions to the emergency department for suicidal behavior. The data collected through this project will ultimately help SAMHSA to understand and direct crisis center follow-up lifesaving initiatives. The data collection activities are described below.

Two funded crisis centers, working in collaboration with two hospital emergency departments, will provide follow-up services to patients seen in the emergency department following a suicide attempt. Patient data will be collected for patients admitted for a suicide attempt in the two years prior to collaboration between the emergency department and crisis center and for patients admitted for a suicide attempt for the 2-year period after collaboration.

(1) The Hospital Data Abstraction Form will be utilized to collect systematic patient data for patients seen in one of the two participating hospital emergency departments. Information to be abstracted from patient data include: Demographic data, historical data, and subsequent suicidal behavioral and admission data. Data will be de-identified. Hospital staff will review patient data for qualifying (i.e., admission to the emergency department for suicide attempt) records. Records to be reviewed will include emergency department admissions for the two years prior to crisis center and hospital emergency department collaboration and for two years following collaboration. It is expected that a total of 2,000 records will be abstracted by hospital staff and provided to the evaluation team.

(2) The Crisis Center Data Abstraction Form will be utilized to collect systematic crisis center data for patient records for whom hospital data were collected. Data will be de-identified and will only contain a patient identification number to match to the patient ID provided through hospital records.

The estimated response burden to collect this information is as follows annualized over the requested 3-year clearance period is presented below:

TOTAL AND ANNUALIZED AVERAGES: RESPONDENTS, RESPONSES AND HOURS

Instrument	Number of respondents	Responses per respondent *	Total number of responses	Burden per response	Annual burden *
Hospital Data Abstraction Form	2	334	667	.04	27
Crisis Center Data Abstraction Form	2	167	333	.04	13
Total	4				40

* Rounded to the nearest whole number.

Written comments and recommendations concerning the proposed information collection should be sent by April 15, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2013–06004 Filed 3–14–13; 8:45 am]

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