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; Interdisciplinary Molecular Sciences Training Member Conflict.

Date: July 2, 2019.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, RKL II, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046B, MSC 7892, Bethesda, MD 20892, 301–408–9655, *gubina@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD–19–018: Clinical Trials Development for Co-Occurring Conditions in Individuals with Down Syndrome: Phased Awards for INCLUDE (R61/R33).

Date: July 8, 2019.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, 301–594–3163, *champoum@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Biology.

Date: July 9, 2019.

Time: 12:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, RKL II, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4158, MSC 7806, Bethesda, MD 20892, 301–435–1256, *biesj@mail.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: June 5, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–12222 Filed 6–10–19; 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: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1112.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

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

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.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms. There are no changes being made to 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 non-compliance.	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
Subtotal		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	1,680
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
Subtotal		1,775		24,594		1868.95
Total		1,829		26,001		2,263.15

Send comments to Janet Heekin, SAMHSA Reports Clearance Officer, Room 15E21–B, 5600 Fishers Lane, Rockville, MD 20850 *OR* email her a copy at *janet.heekin@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: June 6, 2019.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2019–12291 Filed 6–10–19; 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: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1112.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Protection and Advocacy for Individuals With Mental Illness (PAIMI) Final Rule, 42 CFR Part 51 (OMB No. 0930–0172)—Extension

These regulations meet the directive under 42 U.S.C. 10826(b) requiring the Secretary to promulgate final regulations to carry out the PAIMI Act (42 U.S.C. 10801 *et seq.*). The regulations contain information collection requirements associated with the rule. The Act authorizes funds to support activities on behalf of individuals with significant (severe) mental illness (adults) or significant (severe) emotional impairment (children/youth) as defined by the Act at 42 U.S.C. 10802(4) and 10804(d). Only entities designated by the governor of each State, including the American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, U.S. Virgin Islands, District of Columbia (Mayor), and the tribal councils of the American Indian Consortium (the Hopi Tribe and the Navajo Nation located in the Four Corners region of the Southwest), to protect and advocate the rights of persons with developmental disabilities are eligible to receive PAIMI Program grants [ibid at 42 U.S.C. at 10802(2)]. These grants are based on a formula prescribed by the Secretary [ibid at 42 U.S.C. at 10822(a)(1)(A)].

On January 1, each eligible state protection and advocacy (P&A) system is required to prepare an annual PAIMI Program Performance Report (PPR). Each annual PPR describes a P&A system's activities, accomplishments and expenditures to protect the rights of individuals with mental illness supported with payments from PAIMI program allotments during the most recently completed fiscal year. Each P&A system transmit a copy of its annual report to the Secretary (via SAMHSA) and to the State Mental Health Agency where the system is located per the PAIMI Act at 42 U.S.C. 10824(a). Each annual PPR must provide the Secretary with the following information:

- The number of (PAIMI-eligible) individuals with mental illness served;
- A description of the types of activities undertaken;
- A description of the types of facilities providing care or treatment to which such activities are undertaken;
- A description of the manner in which the activities are initiated;
- A description of the accomplishments resulting from such activities;
- A description of systems to protect and advocate the rights of individuals with mental illness supported with payments from PAIMI program allotments;
- A description of activities conducted by states to protect and advocate such rights;
- A description of mechanisms established by residential facilities for individuals with mental illness to protect such rights;
- A description of the coordination among such systems, activities, and mechanisms;
- Specification of the number of public and nonprofit P&A systems established with PAIMI program allotments; and
- Recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of the need for such activities and services that were not met by the state P&A systems established under the PAIMI Act due to resource or annual program priority limitations.

Each PAIMI grantee's annual PPR must include a separate section, prepared by its PAIMI Advisory Council (PAC), that describes the council's activities and its assessment of the state P&A system's operations per the PAIMI Act at 42 U.S.C. 10805(7).

In 2017, SAMHSA included the annual PAIMI PPR in the Web-based Block Grant Application System (WebBGAS). WebBGAS, SAMHSA's electronic data system, is used to collect grantee information for the following reasons:

(1) To meet the OMB requirements for data collection for mandatory (formula) grant programs;

(2) To comply with the annual program reporting requirements of the PAIMI Act, 42 U.S.C. 10801 *et seq.* and the PAIMI Rules 42 CFR part 51;

(3) To simplify the submission of PAIMI Program data by the state P&A systems;

(4) To meet the Government Performance and Results Act (GPRA) requirements;

(5) To comply with the Government Accountability Office (GAO) evaluation recommendations that SAMHSA obtain information that closely measures the actual outcomes of the programs it funds;

(6) To reduce the grantee data collection burden by removing information that did not facilitate evaluation of a PAIMI grantee's programmatic and financial management systems;

(7) To provide immediate access to the PAIMI program data used to prepare a section of the Secretary's biennial report to the President, Congress, and National Council on Disability in accordance with the *Developmental Disabilities Assistance Act of 2000* at 42 U.S.C. 15005. Reports of the Secretary;

(8) To improve SAMHSA's ability to create reports, analyze trends, and provide timely feedback to the P&A grantees when PPR revisions are needed.

On July 17, 2017, OMB approved SAMHSA's PPR and Advisory Council Report (Control No. 0930–0169, Expiration Date July 31, 2020). The burden estimate for the annual state