

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 20, 2016.

Melanie J. Gray-Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Omnibus SEP-3 R03 & R21.

Date: March 21–22, 2016.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Viatcheslav A. Soldatenkov, MD, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W254, Bethesda, MD 20892-9750, 240-276-5378, soldatenkov@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis; Panel Advance Development and Validation of Emerging Molecular Analysis.

Date: March 22–23, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 5W030/4W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Kenneth L. Bielak, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division Of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Bethesda, MD 20892-9750, 240-276-6373, bielatk@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 20, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

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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: Now Is the Time (NITT)—Healthy Transitions (HT) Evaluation—New

SAMHSA is conducting a national evaluation of the Now is the Time (NITT) initiative, which includes separate programs—NITT Project AWARE (Advancing Wellness and Resilience in Education)—State Educational Agency (SEA), Healthy Transitions (HT), and two Minority Fellowship Programs (Youth and Addiction Counselors). These programs are united by their focus on capacity building, system change, and workforce development.

NITT-HT, which is the focus of this data collection, represents a response to the fourth component of President

Obama's NITT Initiative: Increasing access to mental health services. The purpose of the NITT-HT program is to improve access to treatment and support services for youth/young adults 16–25 years that either have, or are at risk of developing a mental illness or substance use disorder, and are at high risk of suicide. NITT-HT grants were made to 17 state or local jurisdictions, each of which include 2–3 learning laboratories (n = 43), which are the local communities of practice responsible for implementing the NITT-HT approach. The NITT-HT program aims to increase awareness about early signs and symptoms of mental health conditions in the community; identify action strategies to use when a mental health concern is detected; provide training to provider and community groups to improve services and supports for youth/young adults; enhance peer and family supports; and develop effective services and interventions for youth and young adults with a serious mental health condition and their families. The NITT-HT evaluation is designed to understand whether and how NITT-HT grantees reach these program goals by examining system- and grantee-level processes and system- and client-level outcomes. Data collection efforts that will support the evaluation are described below.

The *Community Support for Transition Inventory (CSTI)* will assess systems change for communities implementing comprehensive, community-based approaches to improve outcomes for emerging adults with serious mental health conditions. The *CSTI* is organized around seven themes: Community partnership, collaborative action, transition planning quality assurance and support, workforce, fiscal policies and sustainability, access to needed support and services, and accountability. The *CSTI* is a web-based survey to be completed by 1,075 community leaders (15–25 community leaders per 43 learning laboratories) once during Year 2 and once during Year 4 of the grant period. Community leaders include members of the local advisory or steering committee, staff of the NITT-HT program, staff of agencies providing portions of the services, and young adult and family members' advocates.

The *State Support for Transition Inventory (SSTI)* will assess state support for systems change and is organized around six themes (partnership, collaborative action, workforce, fiscal policies & sustainability, access to needed supports & services, and accountability). The *SSTI* is a web-based survey to be

completed by 425 state leadership members (20–25 state leaders per 17 grantees) once during Year 2 and once during Year 4 of the grant period. State leadership members include administrators or staff from state agencies responsible for aspects of services to youth/young adults (e.g., mental health, child welfare, education), youth/young adult and adult allies who are active in promoting, planning, or overseeing services at the state level, as well as other members of state-level advisory groups or governing bodies.

The *Collaborative Member Survey* is designed to assess specific team processes that contribute to collaboration outcomes at the systems level and will be administered to a subset of *CSTI* respondents who participate in a NITT–HT grantee’s Advisory Team. The *Collaborative Member Survey* emphasizes aspects of Advisory Teams’ climate (participatory decision-making, structure, management of conflict, reflexivity). A maximum of 1,075 respondents (15–25 advisory team members per 43 learning laboratories) are expected to complete the web-based survey once during Year 3 and once during Year 5 of the grant period.

The *Collaborative Self-Assessment* assesses collaborative functioning and accomplishments, and specific tasks completed by NITT–HT grantee stakeholders and the leadership team including progress in each of the primary “functions” for the NITT–HT grantees (i.e., specific, discrete achievements or steps toward strategic and fiscal planning, expansion of services, early identification outreach, and reduction of barriers to access). The web-based *Collaborative Self-Assessment Survey* will be completed by one advisory team member per learning laboratory (n = 43) once in Year 3 and once in Year 5 of the grant period.

The *Project Director Web Survey* will collect information on planning, coordination, leadership processes, fiscal planning, and sustainability. The brief *Project Director Web Survey* will be completed by all grantee project directors (n = 17) once during each of Years 2, 3, and 4 of the grant period. The web survey includes prompts designed to assist the project director in gathering and recalling information to be discussed during the subsequent *Project Director Telephone Interview*. Upon completion of the web survey, the project director will be asked to schedule a telephone interview, which will focus on gathering more in depth information to complement information gathered via the web survey. The *Project Director Telephone Interview* includes information on state/local

implementation, fiscal planning, coordination and organizational challenges, workforce development, quality assurance procedures, sustainability planning, and leadership and political issues. The telephone interview will also be completed by all grantee project directors (n = 17) once during each of Years 2, 3, and 4 of the grant period. The web survey and telephone interview are slightly different at each time point to reflect varying annual changes in program implementation emphasis.

The *Core Staff Web Survey* will be administered to core NITT–HT staff to assess characteristics of person-centered practice and barriers to this practice. “Core staff” are defined as staff members serving as primary providers of planning, case management and coordination services to youth/young adults (“life coaches,” “transition facilitators,” or “transition specialists”). A maximum of 430 core staff (no more than 10 core staff per 43 learning laboratories) are expected to complete the *Core Staff Survey* once during the grant period.

In the *Multi-Media Project*, youth/young adults will be invited to voluntarily provide information about their experiences working with or being served by NITT–HT grantee communities using multi-media outlets. Youth/young adult involvement is a priority both for the NITT–HT national evaluation and for NITT–HT grantees. Consequently, it will be important to offer youth/young adults opportunities to participate in national evaluation activities in developmentally-appropriate and engaging ways. These outlets could include videos, photos, blogs, or poems (at the choice of the participating youth/young adult). Youth/young adults will be given informational probes (e.g., what keeps you involved in NITT–HT activities?) in grantee Years 2, 3, and 4; an estimated 510 youth/young adults (30 youth/young adults per 17 grantees) will participate in the *Multi-Media Project*.

The *Supplemental Youth and Youth Adult Interview (SYAI)* will assess key client-level outcomes of interest for the NITT–HT program, including: School/home/daily living functioning, emotional/behavioral health, vocation and education status, housing stability, criminal or juvenile justice involvement, psychotic symptoms, substance use/abuse, trauma symptoms, victimization experiences and propensity to commit violent acts. In addition to primary outcomes of interest, the *SYAI* also assesses intermediate outcomes thought to be critical in influencing change in

behavioral health and functioning, including: Self-efficacy (mental health, school, career and social), and perceptions of social support, person-centered care, and service alliance. The *SYAI* includes standardized instruments as well as project-developed items and does not duplicate the client-level data collection required separately by SAMHSA (OMB No. 0930–0346). The *SYAI* will be conducted with 90 service recipient youth/young adults per NITT–HT grantee (n = 17), for a total of 1,530 youth/young adults, at program enrollment (Baseline) and 12- and 24-months after enrollment. These 90 cases will be evenly distributed across the grantee’s 2–3 learning laboratories. The *SYAI* is designed for administration as an audio computer-assisted self-interviewing (ACASI) survey. This mode was selected to offer participating youth/young adults maximum privacy while completing the interview and to present minimal survey administration burden to NITT–HT grantee staff.

Grantee Visit In-Person Interviews and Focus Group Guides

All NITT–HT grantees (n = 17) will be visited once during the 5-year grant period. Activities associated with the grantee visit (i.e., a pre-planning inventory, interviews, focus groups, and document review) are described below.

Prior to the grantee visit, the *Services & Supports Inventory* will be administered one time by telephone to a representative from each of the NITT–HT grantees (n = 17) to identify specific providers and other stakeholders to participate in the grantee visit. Respondents will also provide information about specific services, especially evidence-based and evidence-informed practices being provided to youth/young adults through NITT–HT associated behavioral health or other professional agencies, and provide a preliminary assessment of the frequency and quality of implementation of the practice(s).

During the one-time grantee visit, several in-person interviews and two client-oriented focus groups will be conducted with NITT–HT program staff. The *Core Staff In-Person Interview* will be conducted with core staff members (i.e., “transitions specialists,” “transition facilitators,” or “life coaches”) to examine their experiences providing person-centered planning services to youth/young adults served within the NITT–HT grantee communities and ask about successes and challenges in creating and implementing youth/young adult service plans. A total of 215 core staff

(five core staff per 43 learning laboratories) are expected to participate.

The *Youth Coordinator In-Person Interview* will be conducted with three staff members (one youth coordinator and up to two peer workers) to elicit staff experiences working with the NITT-HT grantee with a focus on the Youth Coordinator functions including participation in planning and coordination, outreach, mentoring, and other activities. A total of 129 staff members (three per 43 learning laboratories) are expected to participate.

The *Provider In-Person Interview* will be conducted with individuals who provide behavioral health services/treatment directly to youth/youth adults served within the NITT-HT community, other than the transition facilitators. These individuals will likely come from NITT-HT partner organizations. Interviews will focus on two areas: (1) Perceptions of organizational support by the collaborative, and (2) implementation of evidence-based practices (e.g., general attitudes, types of practices being used, implementation supports). A total of 85 key provider informants (five key providers per 17 grantees) are expected to participate.

The *Stakeholder In-Person Interview* will be conducted with other key stakeholders (e.g., board members for agencies, leaders or liaisons for advocacy groups, leaders or advocates

with religious or charitable organizations), as identified by grantee leadership. The interview will elicit experiences contributing to systems development, including history of involvement, their specific contributions to the systems development effort, and strategies, barriers and facilitators to making these contributions. A total of 51 community stakeholders (3 stakeholders per 17 grantees) are expected to participate.

Two *Young Adult Focus Groups* will be conducted during the grantee visit—one for youth/young adults directly involved in NITT-HT system change efforts, and one for youth/young adults who are recipients of NITT-HT services. The focus groups are designed to elicit perceptions based on youth/young adult lived experience about resources to support successful youth/young adult transition at NITT-HT sites, whether practices are well aligned to address needs and cultivate resources, and ideas about how to build on these achievements in the future. An information form will be completed by each participant to gather general background information (e.g., demographics, extent of experience with the mental health system and grantee community). A total of 860 youth/young adult participants (20 participants per 43 learning laboratories) are expected to participate.

Two *Family/Adult Ally Focus Groups* will be conducted during the grantee visit—one focused at the client-level (for family members of youth/young adults service recipients), and one focused at the systems level (for family members involved in NITT-HT grantee planning and systems change efforts). The focus groups will gather information about family member perceived needs and resources to support youth/young adults at the NITT-HT sites. An information form will be completed by each participant to gather general background information (e.g., demographics, extent of experience with the mental health system and grantee community). A total of 860 family/adult allies (20 participants per 43 learning laboratories) are expected to participate.

Grantee Visit Document Review. Files or charts of a subset of youth/young adults participating in the SYAI will be reviewed during the grantee visit. This document review will be designed to ascertain types of standard documentation routinely completed for youth/young adult clients served as well as the consistency of completion of these documents. Information extracted from client charts will be programmatic only; there will be no identifying or personal information extracted from these client charts.

ANNUALIZED BURDEN HOURS FOR THE NITT—HEALTHY TRANSITIONS EVALUATION

Instrument/activity	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Community Support for Transition Inventory	1,075	1	1,075	0.4	430
State Support for Transition Inventory	425	1	425	0.32	136
Collaborative Member Survey	1,075	1	1,075	0.25	269
Collaborative Self-Assessment Survey	43	1	43	0.83	36
Project Director Web Survey	17	1	17	0.33	6
Project Director Telephone Interview	17	1	17	1.5	26
Core Staff Web Survey	430	1	430	0.33	142
Grantee Visits:					
Services & Supports Inventory	17	1	17	0.67	11
Core Staff In-Person Interview	215	1	215	0.33	71
Youth Coordinator In-Person Interview	129	1	129	1	129
Provider In-Person Interview	85	1	85	0.75	64
Stakeholder In-Person Interview	51	1	51	0.75	38
Young Adult Focus Group	860	1	860	1.75	1,505
Family/Adult Ally Focus Group	860	1	860	1.75	1,505
Document Review	43	1	43	0.25	11
Supplemental Youth & Young Adult Interview	1,530	1	1,530	0.67	1,025
Multi-Media Project Young Adult Probes	510	1	510	0.33	168
Total	*5,522	7,382	5,572

* This is an unduplicated count of total respondents.

Written comments and recommendations concerning the proposed information collection should be sent by February 25, 2016 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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Project: Quarterly Progress Reporting and Annual Indirect Services Outcome Data Collection for the Minority Substance Abuse/HIV Prevention Program (MAI)—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting approval from the Office of Management and Budget (OMB) for the collection of quarterly progress information and annual community-level outcome data from CSAP's Minority AIDS Initiative (MAI) programs.

This data collection effort supports two of SAMHSA's 6 Strategic Initiatives: Prevention of Substance Abuse and Mental Illness and Health Care and Health Systems Integration. The grantees funded by the MAI and included in this clearance request are:

- Minority Serving Institutions (MSI) in Partnerships with Community-Based Organizations (CBO): 84 grantees funded up to three years;
- Capacity Building Initiative (CBI): 74 grantees funded up to five years.

MSI CBO grantees are Historically Black Colleges/Universities, Hispanic Serving Institutions, American Pacific Islander Serving Institutions, or Tribal

Colleges/Universities in partnership with community based organizations in their surrounding communities. MSI CBO grantees are required to provide integrated substance abuse (SA), Hepatitis C (HCV), and HIV prevention services to young adults. The CBI grantees are community-level domestic, public and private nonprofit entities, federally recognized American Indian/Alaska Native Tribes and tribal organizations, and urban Indian organizations. CBI grantees will use grant funds for building a solid infrastructure for integrated SA, HIV, and HCV prevention service provision and implementing evidence-based prevention interventions using SAMHSA's Strategic Prevention Framework (SPF) process. The target population for the CBI grantees will be at-risk minority adolescents and young adults. All MAI grantees are expected to provide leadership and coordination on the planning and implementation of the SPF and to target minority populations, as well as other high risk groups residing in communities of color with high prevalence of SA and HIV/AIDS.

The MAI grantees are expected to provide an effective prevention process, direction, and a common set of goals, expectations, and accountabilities to be adapted and integrated at the community level. Grantees have substantial flexibility in choosing their individual evidence-based programs, but must base this selection on and build it into the five steps of the SPF. These SPF steps consist of assessing local needs, building service capacity specific to SA and HIV prevention services, developing a strategic prevention plan, implementing evidence-based interventions, and evaluating their outcomes. Grantees are also required to provide HIV and HCV testing and counseling services and referrals to appropriate treatment options. Grantees must also conduct ongoing monitoring and evaluation of their projects to assess program effectiveness including Federal reporting of the Government Performance and Results Act (GPRA) of 1993, The GPRA Modernization Act of 2010, SAMHSA/CSAP National Outcome Measures (NOMs), and the Department of Health and Human Services Core HIV Indicators.

The primary objectives of this data collection effort are to:

- Ensure the correct implementation of the five steps of the SPF process by maintaining a continuous feedback loop between grantees and their POs;
- Promptly respond to grantees' needs for training and technical assistance;

- Assess the fidelity with which the SPF is implemented;
 - Collect aggregate data on HIV testing to fulfill SAMHSA's reporting and accountability obligations as defined by the Government Performance and Results Modernization Act (GPRA Modernization Act) and HHS's HIV Core Measures;
 - Assess the success of the MAI in reducing risk factors and increasing protective factors associated with the transmission of the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and other sexually-transmitted diseases (STD);
 - Measure the effectiveness of evidence-based programs and infrastructure development activities such as: Outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS counseling and education, testing, referrals to appropriate medical treatment, and other intervention strategies (e. g., cultural enrichment activities, educational and vocational resources, motivational interviewing & brief interventions, social marketing, and computer-based curricula);
 - Investigate intervention types and features that produce the best outcomes for specific population groups;
 - Assess the extent to which access to health care was enhanced for population groups and individuals vulnerable to behavioral health disparities residing in communities targeted by funded interventions;
- These objectives support the four primary goals of the National HIV/AIDS Strategy which are: (1) Reducing new HIV infections, (2) increasing access to care and improving health outcomes for people living with HIV/AIDS, (3) reducing HIV-related disparities and health inequities, and (4) achieving a coordinated national response to the HIV epidemic.
- The Quarterly Progress Reporting (QPR) Tool is a modular instrument structured around the SPF. Each section or module corresponds to a SPF step with an additional section dedicated to cultural competence and efforts to address behavioral health disparities, which is an overarching principle of the framework guiding every step. Grantees provide quarterly reports of their progress through the SPF. Each quarter's report consists of updates to the module(s) corresponding to the SPF steps that the grantee worked on during that quarter. Grantees are required to report on their activities, accomplishments, and barriers associated with cultural competence and reduction of health disparities twice a year, as part of the second- and fourth-