2016–0–CA–05]; Mexican Patent Application Number MX/A/2018/010958 filed March 11, 2017 and entitled ''Live Attenuated Zika Virus Vaccines,'' [HHS Reference No. E–118–2016–0–MX–12]; Brazilian Patent Application Number 1120180683426 filed September 11, 2018 and entitled ''Live Attenuated Zika Virus Vaccines,'' [HHS Reference No. E–118–2016–0–BR–04]; Colombian Patent Application Number NC2018/0010874 filed March 11, 2017 and entitled ''Live Attenuated Zika Virus Vaccines,'' [HHS Reference No. E–118–2016–0–CO–07]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive licensed territory may be limited to the United States of America, Canada, Mexico, Brazil and Colombia, and the field of use may be limited to: ''Monovalent live attenuated Zika vaccines and multivalent live attenuated flavivirus vaccines.''

Zika virus (ZIKV) is an emerging infectious disease that was first identified in 1947, and that has more recently become a major public health threat around the world. ZIKV has recently been shown to cause devastating neurological damage in infants and serious complications in adults in some cases, and may have other effects that have not yet been identified or definitively linked to the virus. There are no treatments or vaccines for this insidious virus. Recommendations that women who live in or travel to endemic areas avoid pregnancy for long periods of time are unrealistic, particularly in contexts where access to reproductive services is limited, and threaten to leave those most likely to suffer the devastating consequences of Zika without effective protection. There is therefore urgent need to develop biomedical interventions in parallel with ongoing public health efforts against ZIKV.

No vaccine exists today to prevent ZIKV infections. The methods and compositions of this invention provide a means for prevention of ZIKV infection by immunization with live attenuated, immunogenic viral vaccines against ZIKV and/or Dengue virus.

Many entities, governmental, academic, and commercial, are actively pursuing development of ZIKV vaccines each using a different approach to address this public health need. The U.S. Government is coordinating its vaccine development response to ZIKV and has published this plan at *https://www.phe.gov/Preparedness/planning/Pages/zika-white-paper.aspx.*

Vaccine development approaches for ZIKV include but are not limited to inactivated virus (dead virus), live attenuated virus (weakened virus), recombinant viral vectors (weakened virus with target genes added), and subunit (portion of a virus) as well as mRNA- and DNA-based (gene-targeted). These various strategies provide multiple redundancies, expanded choice, and ensure short and long term maximal benefits to the public.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the licenses would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: December 11, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–27673 Filed 12–20–18; 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: Technology Transfer Centers (TTC) Network Program Monitoring—NEW

The Substance Abuse and Mental Health Administration's (SAMHSA) will monitor program performance of its Technology Transfer Centers (TTCs). The TTCs disseminate current behavioral health and HIV services research from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, Agency for Healthcare Research and Quality National Institute of Justice, and other sources, as well as other SAMHSA programs. To accomplish this, the TTCs develop and update state-of-the-art, research-based curricula and professional development training.

The TTCs hold a variety of events: technical assistance events, meetings, trainings, and learning collaboratives. A TTC technical assistance event is defined as a jointly planned consultation generally involving a series of contacts between the TTC and an outside organization/institution during which the TTC provides expertise and gives direction toward resolving a problem or improving conditions. Technical assistance events can be categorized into universal, targeted and intensive. Other TTC events such as meetings, training, strategic planning and learning collaboratives are utilized to support technical assistance. These events are TTC-sponsored or co-sponsored events in which a group of people representing one or more agencies other than the TTC work cooperatively on a project, problem, and/or policy.

SAMHSA intends to use five (5) instruments for program monitoring of TTC events as well as ongoing quality improvement, which are described below.

1. *Event Description Form (EDF):* The EDF collects event information. This instrument asks approximately 10 questions of TTC faculty/staff relating to the event focus and format. It allows the TTCs and SAMHSA to track the number of events held (See Attachment 1).

2. *TTC Post Event Form—Domestic:* The Post Event Form—Domestic will be administered immediately following the event. It asks approximately 11 questions of each individual that participated in the event (Attachment 2). The instrument asks the participants

to report on general demographic information (gender, race, level of education, primary profession), principal employment setting, employment zip code, satisfaction with the event, if they expect the event to benefit them professionally, if they expect the event to change their practice and if they would recommend the event to a colleague.

3. *TTC Post Event Form—International:* The Post Event Form—International will be administered immediately following the event. It asks 9 questions of each individual that participated in the event (Attachment 3). The instrument is very similar to the Post Event Form—Domestic and asks the participants to report gender, highest degree received, principal employment setting, employment postal code, satisfaction with the event, if they expect the event to benefit them professionally, if they expect the event to change their practice and if they would recommend the event to a colleague. The main difference between the international and domestic versions of the post event forms is the modification of the demographic questions to make the forms appropriate for distribution outside the U.S. context and relevant to existing PEPFAR indicators. For example, the race/ethnicity questions from the domestic form are not included in the international form. Also, the personal code offers more spaces for characters to provide flexibility in how the personal code is constructed in different countries. Making these change assists SAMHSA in being culturally appropriate (*e.g.,* participants of events of the South Africa HIV ATTC could be offended by being asked if they are ''African American''; the concept of ''mother's maiden name'' does not exist in Vietnam). The change also makes the information better match the needs of PEPFAR, which provides the funding for these centers.

4. *TTC Follow-up Form—Domestic:* The Follow-up Form—Domestic will be administered 30-days after all events that last a minimum of three (3) hours. The form will be administered to a minimum of 25% of participants who consent to participate in the follow-up process. The form asks about 10 questions (Attachment 3). The instrument asks the participants to report if the information provided in at the event benefited their professional development, will change their practice, if they will use the information in their future work, if information will be shared with colleagues, how the event supported their work responsibilities, how the TTC can improve the events, what other topics would participants like to see TTCs address and in what format.

5. *TTC Follow-up Form—International:* The Follow-up Form—International will be administered 30-days after all events that last a minimum of three (3) hours. The form will be administered to a minimum of 25% of participants who consent to participate in the follow-up process. The form asks about 10 questions (Attachment 5). The instrument asks the participants to report if the information provided at the event benefited their professional development, will change their practice, if they will use the information in their future work, if information will be shared with colleagues, how the event supported their work responsibilities, how the TTC can improve the events, what other topics would participants like to see TTCs address and in what format. The only difference between the domestic and international follow-up forms is that the international form offers more spaces for characters for the personal code to provide flexibility in how the personal code is constructed in different countries. While the instruments administered immediately at the end of each event are given to all participants, the instruments administered 30 days after each event are sent to a random sample of 25% of those participants who consented to follow-up. This sampling rule applies to all events that last a minimum of three (3) hours.

The information collected on the TTC forms will assist SAMHSA in documenting the numbers and types of participants in TTC events, describing the extent to which participants report improvement in their professional development, and which method is most effective in disseminating knowledge to various audiences. This type of information is crucial to support SAMHSA in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The chart below summarizes the annualized burden for this project.

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annual burden hours
ATTC Faculty/Staff					
Event Description Form	250	1	250	.25	62.50
Meeting and Technical Assistance Participants					
Post-Event Form	5,000	1	5,000	.12	600
Follow-up Form	Covered under CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB # 0930–0197)				
Training Participants					
Post-Event Form	30,000	1	30,000	.16	4,800
Follow-up Form	7,500	1	7,500	.16	1,200
Total	42,750		42,750		6,662.50
MHTTC Faculty/Staff					
Event Description Form	250	1	250	.25	62.50
Meeting and Technical Assistance Participants					
Post-Event Form	5,000	1	5,000	.12	600

Follow-up Form	Covered under CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB # 0930–0197)				
Training Participants					
Post-Event Form	30,000	1	30,000	.16	4,800
Follow-up Form	7,500	1	7,500	.16	1,200
Total	42,750		42,750		6,662.50
PTTC Faculty/Staff					
Event Description Form	250	1	250	.25	62.50
Meeting and Technical Assistance Participants					
Post-Event Form	5,000	1	5,000	.12	600
Follow-up Form	Covered under CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB # 0930–0197)				
Training Participants					
Post-Event Form	30,000	1	30,000	.16	4,800
Follow-up Form	7,500	1	7,500	.16	1,200
Total	42,750		42,750		6,662.50

SUMMARY TABLE

Instruments	Number of respondents	Responses per respondents	Burden hours
TTC Event Description Form	750	1	187.50
TTC Post Event Form—Domestic and International	105,000	1	16,200
TTC Follow up Form—Domestic and International	22,500	1	3,600
Total	128,250	1	19,987.50

Written comments and recommendations concerning the proposed information collection should be sent by January 22, 2019 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. 2018–27634 Filed 12–20–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council (NAC) will meet on February 27, 2019, 9:00 a.m.–5:00 p.m. (EDT).

The meeting is open and will include consideration of minutes from the SAMHSA CSAT NAC meeting of August 1, 2018; the Director's Report; updates from the Division Directors; a budget update; discussions on recovery housing; discussions with SAMHSA leadership; and discussions expanding access to Medication-Assisted Treatment.

The meeting will be held at SAMHSA, 5600 Fishers Lane, Room 5N54, Rockville, MD 20857. Attendance by the public will be limited to space available and will be limited to the open sessions of the meeting. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before February 1, 2019. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person on or before February 1, 2019. Five minutes will be allotted for each presentation.

The open meeting session may be accessed via telephone. To attend on site, or to obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at *http://nac.samhsa.gov/Registration/meetingsRegistration.aspx,* or communicate with the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at *http://www.samhsa.gov/about-us/advisory-councils/csat-*