Place: National Institutes of Health, Rockledge 6700, Room 3185, MSC 6908, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Barbara J Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892–9306, 301–402–0838, *barbara.thomas@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: October 5, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–22315 Filed 10–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Lentiviral Protein Delivery System for RNA-Guided Genome Editing

Available for licensing and commercial development is an HIV–1-based lentiviral vector system for gene correction strategies involving a homologous recombination with a variation of the CRISPR/Cas9 system. Other such lentivirus-based vectors encode a guide RNA, which contains a specific sequence that recognizes a target gene, and a Cas9 endonuclease, which cuts at the specific site. Such systems are being explored as potential therapies for certain hereditary diseases (*e.g.,* sickle-cell disease). However, such systems present some problems due to constitutive expression of Cas9 endonuclease in lentiviral vector-transduced cells and the large size of the Cas9 gene. The variation of this invention delivers the Cas9 endonuclease directly, instead of the gene encoding the protein. This system comprises (a) a lentivirus vector particle comprising a lentiviral genome which encodes at least one guide RNA sequence that is complementary to a first DNA sequence in a host cell genome, (b) a Cas9 protein, and optionally (c) a donor nucleic acid molecule comprising a second DNA sequence. In addition, the invention provides a host cell comprising the foregoing system, as well as a method of altering a DNA sequence in a host cell comprising contacting a host cell with the foregoing system. Alternatively, the invention also provides a fusion protein comprising a Cas9 protein and a cyclophilin A (CypA) protein, wherein the fusion protein binds to the lentivirus vector particle, as well as a lentiviral vector particle comprising such a fusion protein. Gene correction using the disclosed lentiviral vector systems are being tested with respect to the beta-globin gene and the BCL11A gene (to treat sickle-cell disease) and will be used for induced pluripotent stem cell (iPS) generation.

Potential Commercial Applications:

- Sickle cell disease
- gene therapy

Development Stage:

- Early stage

Inventors: Naoya Uchida, Juan J. Haro Mora, John F. Tisdale (all of NHLBI)

Relevant Publications: Demirci et al., Cytotherapy. 2018 Jul;20(7):899–910. doi: 10.1016/j.jcyt.2018.04.003. Epub 2018 May 30.

Intellectual Property: HHS Reference No. E–165–2015; U.S Provisional Patent Application 62/236,223 filed October 2, 2015; International Patent Application PCT/US2016/054759 filed September 30, 2016, U.S. Continuation-in-Part Application 15/942,673 filed April 2, 2018 and European Patent Application 16782163.6 having an international filing date of September 30, 2016.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Dated: October 4, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018–22360 Filed 10–12–18; 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: 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) 276–1243.

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: 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).				

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annual burden hours
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

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annual burden hours
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

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annual burden hours
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 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

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 15E57–B, 5600 Fishers Lane, Rockville, MD 20852 *or* email a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received by December 14, 2018.

Summer King,

Statistician.

[FR Doc. 2018–22409 Filed 10–12–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1853]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table