



Memorandum

Date November 15, 2012

From Deputy Associate Director for Science, CDC
Office of the Associate Director for Science

Subject Authorization to Extend 308(d) Assurance of Confidentiality Protection for the "Program Evaluation and Monitoring System (PEMS) data," which has been renamed "National HIV Prevention Program Monitoring and Evaluation (NHM&E)."

To

Dr. Linda Valleroy
Associate Director for Science, Division of HIV/AIDS Prevention (DHAP); National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

This memo is to provide formal approval of NCHHSTP's request to receive continued authorization to assure confidentiality under Section 308(d) of the Public Health Service Act for the "Program Evaluation and Monitoring System (PEMS) data," which has been renamed "National HIV Prevention Program Monitoring and Evaluation (NHM&E)."

For ongoing projects, CDC practice is that every five years, the program must apply for a formal extension of the 308(d) authority. Please apply for the extension at least six months prior to September 13, 2017.

Please use 42 USC 242(k), and 42 USC 242(m) as the legal references for information collection and protection.

If you have any questions, please contact Joseph Rush Jr. Confidentiality Administrator, at (404) 639-4772.

Tanja Popovic, M.D., Ph.D., F(AAM), AM(AAFS)
Deputy Associate Director for Science, CDC

cc:
Janet Heitgerd PhD



REQUEST FOR AUTHORIZATION TO GIVE ASSURANCE OF CONFIDENTIALITY UNDER SECTION 308(d) OF THE PUBLIC HEALTH SERVICE ACT

NOTE: Do not obtain signature on this form until OCSO and the Project Officer have agreed on final versions of the 308(d) Justification, Assurance, and Security Statement.
(See "Assurance of Confidentiality Application Procedure" for instructions on completing this form.)

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|--|--|----------------------------------|-------------------------------------|
| 1. REQUESTED BY: | | | |
| Name of Project Officer/Principal Investigator: <u>Janet Heitgerd (for the Program Evaluation Branch)</u> | Bldg/Rm No.: Corp Sq <u>2082</u> | MailStop: <u>E-59</u> | Phone No.: <u>(404) 639-1801</u> |
| Center/Institute/Office: <u>NCHHSTP</u> | Division: <u>Division of HIV/AIDS Prevention (DHAP)</u> | | |
| Request Status: <input type="checkbox"/> New <input type="checkbox"/> Amended Request <input checked="" type="checkbox"/> Extension Request | Period of time authorization needed for data collection: (Indicate "ongoing" if project will continue indefinitely.) From: <u>9/13/2012</u> To: <u>9/2017; indef</u> | | |
| Approval of Request by Center/Institute/Office Director or Designee: | | | |
| <u>HINDA A VALLEROY</u> <u>DHAP/ADP</u> Name and Organizational Title | | <u>H.A. Vallero</u> Signature | <u>11/9/12</u> Date |
| 2. TITLE OF PROJECT: | | | |
| <u>Extension and Amendment of Assurance of Confidentiality for the National HIV Prevention Program</u> | | | |
| <u>Monitoring and Evaluation (NHM&E) Data (formerly the Program Evaluation and Monitoring System (PEMS))</u> | | | |
| 3. JUSTIFICATION STATEMENT: | | | |
| <u>Please attach the justification statement. (See "Assurance of Confidentiality Application Procedure" for further details.)</u> | | | |

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| 4. - FOR OCSO USE ONLY - | |
| Transmitted to Confidentiality Review Group: <u>8/24/2012</u> Date | |
| Confidentiality Review Group recommends: <input checked="" type="checkbox"/> Approval <input type="checkbox"/> Disapproval <u>8/28/2012</u> Date | |
| -- ASSURANCE OF CONFIDENTIALITY IS AUTHORIZED -- | |
| Signature: <u>[Signature]</u> CDC ASSOCIATE DIRECTOR FOR SCIENCE <u>11-19-12</u> Date | |

Memorandum

Date: August 23, 2012

To: Joseph Rush Jr., Confidentiality Administrator

From: David Davis and Janet Heitgerd

Subject: The Program Evaluation and Monitoring System (PEMS) Assurance of Confidentiality (renamed NHM&E Assurance of Confidentiality)

This is an official request for extension of Assurance of Confidentiality under Public Health Services Act Section 308(d) for the "Program Evaluation and Monitoring System (PEMS) data," which has been renamed "National HIV Prevention Program Monitoring and Evaluation (NHM&E)"

I. Extent of Changes to Protocol:

(Includes basic information, a statement that no substantive changes have occurred, and summary of non- substantive changes):

In September 2007, the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention received approval of its request for assurance of confidentiality protection under Section 308(d) of the Public Health Service (PHS) Act for "The Program Evaluation and Monitoring System (PEMS)" data collection. Since the original Assurance of Confidentiality was issued, there have been several changes that are detailed below. The level of security has not been impacted.

Data Submission Method. CDC no longer supports the web-based software developed by CDC to collect the Program Evaluation and Monitoring System (PEMS) data. All funded health jurisdictions and community-based organizations (CBOs) under CDC HIV prevention program funding announcements must submit required data now called National HIV Prevention Program Monitoring and Evaluation (NHM&E) HIV testing and program data to CDC through an approved CDC Data System. CDC is currently using EvaluationWeb® (EvalWeb) for HIV testing data, which will also be required for other program data submissions beginning Fall 2012. This is a secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting program data. The level of security is at least equal to the PEMS software.

Name Change. Given the movement away from the PEMS software, we are requesting a name change for extension of the AOC to "The National HIV Prevention Program Monitoring and Evaluation (NHM&E) Data."

Project Personnel. David Davis replaces Gene A. Shelley as the project officer/principal investigator for the Program Evaluation Branch.

Project Sites. CDC continues to fund health departments and CBOs to implement HIV prevention efforts under CDC HIV prevention program funding announcements. In 2012, 67 health departments were funded (the number of directly-funded city health departments increased from six to eight by adding Atlanta and Baltimore). CBO recipients vary by funding announcement.

We have updated our Confidentiality Security Statement that is being submitted as an attachment along with this extension request: The changes to the security statement are comprehensive in nature. A brief overview of the changes are as follows:

1. As noted in the memo submitted in June, CDC no longer supports the web-based software developed by CDC to collect the Program Evaluation and Monitoring System (PEMS) data. All funded health jurisdictions and community-based organizations (CBOs) under CDC HIV prevention program funding announcements must submit required data now called National HIV Prevention Program Monitoring and Evaluation (NHM&E) HIV testing and program data to CDC through an approved CDC Data System. CDC is currently using EvaluationWeb® (EvalWeb) for HIV testing data, which will also be required for other program data submissions beginning Fall 2012. This is a secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting program data. The EvalWeb application and databases are supported by Luther Consulting, LLC.

2. The security requirement has changed from a rating of moderate to low, according to FIPS Pub 199 and NIST (SP) 800-60.

3. EvalWeb does not use SDN but it does use Secure Socket Layer/Transport Layer Security (SSL/TLS) software to encrypt data between EvalWeb and CDC.

4. Backup of the system is performed by Luther Consulting, LLC.

5. EvalWeb users will be authorized and e-authenticated.

6. The process for reporting and mitigating breach of NHM&E data confidentiality is detailed.

II. Utilization of Confidentiality Protection:

The 308(D) has not been used by any funded agency to prevent disclosure of private data.

III. Why Confidentiality Protection is still needed:

While the Assurance of Confidentiality has not been utilized by any funded sites, it is still needed due to the sensitive nature of NHM&E data collected by health jurisdictions and CBOs.

HIV testing data and other NHM&E program data submitted to CDC through EvalWeb will not contain individually identifiable variables (e.g., individual's names or locating information) but will include select demographic and personal characteristics (gender, race, ethnicity, year of birth, pregnancy status, and HIV status) in addition to intervention and behavioral characteristics. Although data submitted to CDC will not include individuals' names, there remains a possibility that persons may be indirectly identified as being HIV-infected or as having specific behavioral risks for contracting or transmitting HIV. This may pose a threat to confidentiality if unauthorized persons obtain access to this information. All CDC personnel with access to NHM&E data will be required to adhere to a strict security and confidentiality protocol, participate in annual security and confidentiality training, and sign a 308(d) Nondisclosure Agreement and an NHM&E data Rules of Behavior agreement.

NHM&E involves the collection of highly sensitive data, much of it concerning socially stigmatizing conditions or behaviors. The cooperation of health departments, CBOs, and individuals will be very difficult to obtain if concerns about privacy and confidentiality are not addressed. The request for an Assurance of Confidentiality represents an attempt to safeguard data collected in HIV prevention programmatic activities. The Assurance of Confidentiality will be provided on request from the state health department or CBO.