

# US Department of Health and Human Services

## Privacy Impact Assessment

**Date Signed:**

12/14/2017

**OPDIV:**

SAMHSA

**Name:**

Coordinated Specialty Care Evaluation

**PIA Unique Identifier:**

P-3806236-351991

**The subject of this PIA is which of the following?**

Major Application

**Identify the Enterprise Performance Lifecycle Phase of the system.**

Implementation

**Is this a FISMA-Reportable system?**

Yes

**Does the system include a Website or online application available to and for the use of the general public?**

Yes

**Identify the operator.**

Agency

**Is this a new or existing system?**

New

**Does the system have Security Authorization (SA)?**

No

**Indicate the following reason(s) for updating this PIA.****Describe the purpose of the system.**

The Substance Abuse and Mental Health Administration (SAMHSA), in partnership with the National Institute of Mental Health (NIMH) and the Office of the Assistant Secretary for Planning and Evaluation, is designing and implementing an evaluation to assess the relationship between fidelity of selected coordinated specialty care (CSC) programs and mental health consumer (patient) outcomes.

The SAMHSA Mental Health Block Grant program provides funding to states for the provision of mental health services. The Fiscal Year (FY) 2016 Appropriations Act increased the proportion of Mental Health Block Grant funds that states must set aside to initiate or support evidence-based CSC programs. CSC programs assist people who are young and starting to experience psychotic symptoms related to serious mental illness (also referred to as first episode psychosis [FEP]) by providing them with coordinated health care, substance abuse and mental health care, and social services such as supported employment.

This CSC Evaluation/study includes up to 40 sites that are implementing CSC using block grant funding. Across all sites, fidelity to the CSC model will be assessed along with social, clinical and functional outcomes of individuals enrolled in the CSC program. The study specifically focuses on the following:

The relationship between level of fidelity to the CSC model and consumer outcomes;  
Identifying the “active ingredients,” or the most effective components of CSC, that positively impact consumer outcomes;  
Identifying local adaptations of the CSC model to meet the needs of consumers, and how these changes effect consumer outcome.

Study data will be collected about patients at Baseline; 6-Month, 12-Month, and 18-Month Reassessments; or Discharge (if discharged before 18 months). De-identified patient medical records data will also be provided by the study sites and stored on secured data servers for data extraction.

**Describe the type of information the system will collect, maintain (store), or share.**

Data collected on patients will include the following:

"Minimum Data Set" to include gender, race, age, marital status, and other CSC-related study information.

Medical records information

Patient data will also include data collected from these various, standardized CSC-program related forms:

"Modified Colorado Symptom Index"

"Lehman Quality of Life Global Rating Scale"

"Global Functioning Social and Role Scales"

"MIRECC GAF Symptom Scale"

"MIRECC GAF Social Scale"

"MIRECC GAF Occupational Scale"

"Brief Psychiatric Rating Scale"

(MIRECC = "Mental Illness Research, Education, and Clinical Center"; GAF = "Global Assessment of Functioning")

Each site participating in the CSC Evaluation will complete a simple site survey capturing basic information about the site that will include the location of the grantee site, background information on the psychosis program they support, program services provided by the site, a summary of client outcomes, basics on program financing, and fidelity assessment data.

All users of the system, whether system or study administrators, SAMHSA staff, non-direct contractors, or grantee/site data entry personnel, will provide their Name, Email Address, and Phone Number to have their user credentials (username and temporary password) created. At first login they will change their temporary password to one that they select/enter.

**Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.**

SAMHSA, in partnership with NIMH and the Office of the Assistant Secretary for Planning and Evaluation, is designing and implementing an evaluation to assess the relationship between fidelity of selected coordinated specialty care (CSC) programs and mental health consumer (patient) outcomes. Data collected in the evaluation system will not be shared with anyone not associated with the study.

For the evaluation, the system will collect various MIRECC, GAF, and CSC-related information as described above. Site survey data is collected as a baseline for analyzing and comparing the patient data. Patient data is collected to assess the impact of the CSC programs on patient outcomes.

User data is collected to establish their accounts in the system, and to assign them to their specific role within the system.

**Does the system collect, maintain, use or share PII?**

Yes

**Indicate the type of PII that the system will collect or maintain.**

Name

E-Mail Address

Phone Numbers

Medical Records Number

Medical Notes

User credentials (username and password)

**Indicate the categories of individuals about whom PII is collected, maintained or shared.**

Employees

Business Partner/Contacts (Federal/state/local agencies)

Vendor/Suppliers/Contractors

Patients

**How many individuals' PII is in the system?**

100-499

**For what primary purpose is the PII used?**

The PII collected from grantee and system users (name, email address, and phone number) is used for accounts provisioning to the system. The clinical consumer PII (race, gender, age, and marital status) is part of the data to be collected that will be used in the evaluation of grants.

**Describe the secondary uses for which the PII will be used.**

N/A Secondary uses for PII will not be used for testing, training, or research.

**Identify legal authorities governing information use and disclosure specific to the system and program.**

N/A

**Are records on the system retrieved by one or more PII data elements?**

No

**Identify the sources of PII in the system.**

Email

Online

**Government Sources**

Within OpDiv

State/Local/Tribal

## **Non-Governmental Sources**

Private Sector

### **Identify the OMB information collection approval number and expiration date**

The OMB Number is 0930-0376 with an expiration date of 08/31/2020.

### **Is the PII shared with other organizations?**

No

### **Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.**

Patients at each of the CSC sites are consented to participate in the study in accordance with the guidelines of the Internal Review Board (IRB) or other governing body at each individual site. The patient is informed of the data that will be used in the study before consent is obtained from the patient.

System administrators at the prime contractor, data entry personnel at each of the CSC sites, and any other "non-patients", are notified their personal information (name, phone number, and email address) is collected to provide them with access to the system as part of their job functions in support of the project/study.

### **Is the submission of PII by individuals voluntary or mandatory?**

Voluntary

### **Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.**

There is no option to opt-out - PII for account provisioning is required as part of their continued participation in the grants.

### **Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.**

Do not anticipate major changes that would require adjustment to current requirements. Changes to use of data (approved by OMB), would only be applicable to 'new' data collection consent agreements. Data collected under the current consent agreements would be held to required/agreed consent from participants.

### **Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.**

PII is collected only for grantees using the system to report directly into the Evaluation Web site. Grantees will have direct access to the system to enter and edit their PII data. Strict adherence to current security policies ensures integrity in the collection, storage and use of data with integrated measures to address and resolve non-compliance. Records in the system are not directly retrieved by PII.

### **Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.**

Periodic data reviews will be performed to ensure that only approved PII is collected. Consumer/client IDs are de-identified and regular checks will be conducted against those identifiers and data collected to comply with contractual requirements for data integrity, availability, accuracy and relevancy.

### **Identify who will have access to the PII in the system and the reason why they require access.**

#### **Users:**

Users are the Grantees - role-based controls will dictate access rights.

#### **Administrators:**

Non-direct contractors provide the study administration and support.

**Developers:**

Test data is used during development. Developers have access to the Production site for systems support (deployment of new site releases, extraction and delivery of data, reporting, etc.) as approved/authorized by Data Use Agreement (DUA) and the user authorization matrix. All developers are non-direct contractors.

**Contractors:**

Non-direct contractors provide the study and system administration and support.

**Others:**

Researchers for data analyses and evaluation and only with valid and approved DUA agreements.

**Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.**

Access to data is based on the roles of users as authorized by the project manager and the information system manager. Granulated rights at both application and server levels will utilize a responsibilities/authorization matrix ranging from public user (non-credentialed access to general information/text areas) to system administrators (full rights). Integrated system validation controls regulate access and checks will be put into place to monitor and enforce activation, expiration, renewal and deactivation of user accounts.

**Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.**

Job function determines level of access and users are assigned only those rights necessary to fulfill responsibilities for approved roles. System-level audit controls safeguard and audit use.

**Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.**

Privacy and Security training provided at on-boarding; and annual refresher training is provided and mandatory. Human Subjects Protection training are provided to all personnel using the system.

**Describe training system users receive (above and beyond general security and privacy awareness training).**

Additional training for data collection, the use of data in analyses, and other task-specific training is provided as needed.

**Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?**

Yes

**Describe the process and guidelines in place with regard to the retention and destruction of PII.**

PII collected after consent of participants and as approved by contract will remain on secured CSC Evaluation server(s) until a request is made to move/remove/transition or destroy data. Daily backup of servers follow Advanced Encryption Standard (AES) controls and corporate controls regulate restore/upgrade operations as needed. Upon completion of the contract, data will be transitioned to government possession or as directed. Contract does not require National Archives and Records Administration (NARA) schedules.

**Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.**

This system is classified as a Moderate Application and all personnel (staff and contractors) and processes comply with the NIST 800-53 controls required to operate. These include:

Administrative controls such as:  
Contractor Agreements  
System Security Plan (SSP)

PII policies; security awareness and training

Technical and physical controls such as:

Redundancy measures

Backup systems

Encrypted media

Firewalls, encryption, intrusion detection

Role-based authorization and authentication with expiration and renewal limits; timeout controls for inactivity

Audit logs

Identification and data entry cards.

**Identify the publicly-available URL:**

TenPercentEval@samhsa.gov (site not available until after security authorization approved in mid- to late-November 2017).

Note: web address is a hyperlink.

**Does the website have a posted privacy notice?**

Yes

**Is the privacy policy available in a machine-readable format?**

Yes

**Does the website use web measurement and customization technology?**

Yes

**Select the type of website measurement and customization technologies is in use and if it is used to collect PII.**

Session Cookies that do not collect PII.

**Does the website have any information or pages directed at children under the age of thirteen?**

No

**Does the website contain links to non- federal government websites external to HHS?**

No

**Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?**

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