Date Signed:  
02/15/2017  

OPDIV:  
HRSA  

Name:  
Assessing Client Factors Associated with Detectable Viral Load  

PIA Unique Identifier:  
P-8638599-332500  

The subject of this PIA is which of the following?  
Electronic Information Collection  

Identify the Enterprise Performance Lifecycle Phase of the system.  
Initiation  

Is this a FISMA-Reportable system?  
No  

Does the system include a Website or online application available to and for the use of the general public?  
No  

Identify the operator.  
Agency  

Is this a new or existing system?  
New  

Does the system have Security Authorization (SA)?  
No  

Describe the purpose of the system.  
The purpose of the system is to support the study in the collection and maintenance of data gathered via Electronic Medical Record (EMR) abstraction, provider and client interviews and survey, and data extraction from Ryan White HIV/AIDS Program Services Report (RSR) client data. The data will be analyzed and findings used to support Ryan White HIV/AIDS Program (RWHAP) in efforts to increase program effectiveness in helping clients achieve and maintain viral suppression.  

Describe the type of information the system will collect, maintain (store), or share.  
Client Interview (Client perception of): challenges, barriers and facilitators of ability to achieve and maintain viral suppression including effects of stigma and life stressors. This interview includes both survey questions and open-ended responses. Names will be collected and used for the purpose of conducting the chart/record abstraction (see below). Names will not be included or used as part of the analytic data set and will be destroyed upon completion of the site visit. This data will be collected in-person. The interview data will be entered by Abt (company name) staff into NVIVO (company name) and stored on the Abt project system.
Chart/Records Abstraction: Insurance/coverage type; service utilization; health outcomes medical history, health status, other health conditions; data related to HIV and other overall health concerns; Pharmaceutical prescriptions. This information will be abstracted from the site’s electronic health record and (as necessary and feasible) from billing systems, case management records, and RWHAP client services databases. Names will be collected only for purposes of identifying records of those participating in client interview (above). Names will not be included or used as part of the analytic data set and will be destroyed upon completion of the site visit. No personally identifiable information will be collected from the charts/records. This information will come into the Abt system via a secure web-based data entry system that will upload the data into the Abt system at the time of data entry. Users of the Abt project system must sign in using a username (first and last name) and password to access the system.

RSR Client Data: Viral load; Insurance type; Service utilization; demographics. A RSR unique ID will be generated to link to other RSR data records. This data will be provided to Abt (contractor) by HAB from its RSR system via secure FTP to the system.

Site Survey: Perceived or real barriers for clients to achieve and maintain viral suppression; other barriers to health outcomes; health care coverage type; Cost sharing burden by coverage type; Ryan White HIV/AIDS Program (RWHAP) services provided; pharmaceutical coverage and associated cost-sharing for clients, Types of Antiretroviral (ART) drugs used, history of ART use. Personally identifying information (name and email) will be used to identify the correct RWHAP staff person (i.e., Ryan White site program director) and to address the email correctly. This data will come into the Abt system via a secure web-based survey system (Fluid Survey). The data will be automatically uploaded into the Abt project system.

Provider Interview (Provider perception of): challenges for clients to achieve and maintain viral suppression. Names, emails and phone numbers of RWHAP staff will be collected and used for the purpose of contacting and scheduling interviews. Names, emails or phone numbers will not be included or used as part of the analytic data set. This data will be collected through in-person interviews. The interview data will be entered by Abt staff into analytic software - NVIVO (company name) and stored on the Abt project system.

Client Focus Groups (Client perception of): challenges, barriers and facilitators of ability to achieve and maintain viral suppression including effects of stigma and life stressors. This data will be collected in-person. The interview data will be entered by Abt staff into analytic software – NVIVO and stored on the Abt project system.

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

Client Interview (Client perception of): See response to Question 12 above for topics addressed. This interview includes both survey questions and open-ended responses. Names will be collected and used for the purpose of scheduling interviews and conducting the chart/record abstraction (see below). Names will not be included or used as part of the analytic data set and will be destroyed upon completion of the site visit. This data will be collected in-person. The interview data will be entered by Abt staff into NVIVO and stored on the Abt project system.

Chart/Records Abstraction: See response to Question 12 above for topics addressed. This information will be abstracted from the site’s electronic health record and (as necessary and feasible) from billing systems, case management records, and RWHAP client services databases. Names will be collected only for purposes of identifying records of those participating in client interview (above).
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RSR Client Data: See response to Question 12 above for topics addressed. A RSR unique ID will be generated to link to other RSR data records. This data will be provided to Abt (contractor) by HAB from its RSR system via secure FTP to the system.

Site Survey: See response to Question 12 above for topics addressed. Personally identifying information (name and email) will be used to identify the correct RWHAP staff person (i.e., Ryan White site program director) and to address the email correctly. This data will come into the Abt system via a secure web-based survey system (Fluid Survey). The data will be automatically uploaded into the Abt project system.

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Users of the Abt system must sign in using a username (first and last name) and password to access 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 Notes
- User credentials (first and last name) 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
- Administrators at RWHAP sites/providers

How many individuals' PII is in the system?
500-4,999

For what primary purpose is the PII used?
Contact information of administrators at RWHAP sites/providers will be used to setup/coordinate data collection (interviews, EMR abstraction, focus groups, etc.). Name of interviewees will be collected during in person interviews. Collect names of patients for EMR abstraction, however names and other PII of patients are not removed from the site or maintained on the system. Only de-identified medical records are abstracted. A RSR unique ID will be generated to link to other RSR data records.

Describe the secondary uses for which the PII will be used.
N/A

Identify legal authorities governing information use and disclosure specific to the system and program.
5 USC 301, Departmental Regulations

Are records on the system retrieved by one or more PII data elements?
No

Identify the sources of PII in the system.

- Directly from an individual about whom the information pertains
  - In-Person
  - Email
  - Other

- Government Sources
  - Within OpDiv
  - State/Local/Tribal

- Non-Governmental Sources
  - Private Sector
Identify the OMB information collection approval number and expiration date
OMB is in process - no OMB approval number or expiration date is available.

Is the PII shared with other organizations?
Yes

Identify with whom the PII is shared or disclosed and for what purpose.

Within HHS
De-identified data file for further research purposes within HHS.

Private Sector
PII is shared with Abt Associates for conducting data collection for the purpose of contacting sites to arrange data collection.

Describe any agreements in place that authorizes the information sharing or disclosure.
Data use agreements with individual RWHAP sites providing EMR abstraction data.

Describe the procedures for accounting for disclosures.
The data will not be shared outside of HRSA and Abt Associates. In the event that an individual requests data from this system, HRSA will account for the disclosure.

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.
Personal information will be gathered directly from individuals at RWHAP sites via email or phone when the project team reaches out to coordinate data collection. Individuals at RWHAP sites will be given oral notice for phone calls and written notice for emails that their personal information will be collected. Electronic health record data are collected in a HIPAA de-identified manner.

PII is for scheduling interviews and contacting site directors for web surveys will be maintained on Abt's secure servers. Only the Abt study team will have access to these folders. Access can only be granted to staff with the permission of the study Project Director. Files within the secure folders will be reviewed for accuracy by the study Project Director. Abt's servers are backed up every 24 hours.

As part of the overall HAB data collection process, they collect PII to facilitate their mission. This information is shared with the system to generate a participant's user account. A privacy notice on the website provides information regarding the collection of their personal information.

For all non-participants like administrators or analysts, they were asked for their information and notified that this is to create a user account.

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.
Ryan White HIV/AIDS Program staff can choose not to participate in this study and can opt-out at any point during the interview process. After an individual has enrolled, their data cannot be removed because there is no link between the individual and their data.

Prior to data collection, the individual must contact their health provider site to state that they do not wish their data to be collected as part of the study. After the data is collected, individuals cannot opt-out of the data collection and abstraction because there is no way to reverse identify the data using the Ryan White Services Report unique identifier.
Provider personal information is transferred from the RSR system to the project system. Therefore, the RSR system is responsible for providing a method for individuals to opt-out of the collection or use of their personally identifiable information.

For all non-participants like administrators or analysts, they cannot opt-out of the collection of their user credentials because it is required for creating their user accounts.

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

Informed consent will be required for participation in focus groups and individual client interviews. Client staff will approach clients to obtain permission. Other than the contact information of an individual at the study site for the purpose of coordinating data collection, no other PII is collected. Regardless, all data will be transmitted securely and will be maintained on secure servers.

Should there be any unanticipated changes, all participating site staff will be contacted by Abt Associates via email and phone immediately.

**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.**

In the event that an individual's data abstraction has been inappropriately obtained, the individual must contact the health provider site. HRSA and Abt Associates will not have enough information to correct any inaccuracies and will not have enough data to know about whom the data was disclosed.

For interviewees, they must contact the Abt Associates study team or Abt Associates Institutional Review Board via the contact information provided on the consent form.

For system administrators concerned about PII (user credentials) being inappropriately obtained, they must contact Abt Associates Office of Cybersecurity.

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

Personally identifiable information is not periodically reviewed for accuracy. If an error occurs during execution of the system processes, the project team manually reviews and asks the data provider for an update. If the personally identifiable information is not accurate, there is no impact to the participant or the system users’ access to any service other than participating in the survey and interview. Personally identifiable information is for scheduling interviews and contacting site directors for web surveys will maintained on Abt's secure servers. Files within the secure folders will be reviewed for accuracy by the study Project Director.

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

**Users:**

Require site contact information to schedule data collection.

**Administrators:**

By nature of their job's responsibility. They have no need to ever access PII except for system maintenance.

**Contractors:**

Require site contact information to schedule data collection. Contractors are direct contractors.

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

User and direct contractors must be approved by HRSA to access the data. Within HRSA, the HRSA project team reviews any data access requests. The data are de-identified.

The direct contractor, Abt Associates, has been allowed to access the data.
Abt Associates requires that any Abt Associates user must be approved by the Abt Associates project lead before accessing the data. Abt Associates will also have no access to de-identified data.

Administrators, by the nature of their job, have access to the project data. However, the data stored on the system are de-identified. The Abt Associates project lead does NOT review administrator access, but all administrators have been trained on how to handle PII.

**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.**

The access request to the data is reviewed directly by the Project Director to determine if the request is valid. To make sure it is minimum amount, the data is partitioned into the basic user types: Scheduler, interviewer, records extractors, web survey administrator, data analysts. The first 3 have access to participant PII as needed for their job. This is contained in the web survey and scheduling component of the system. The web survey administrator has access to everything by the nature of the job. This function is limited to the 1 individual needed. The analysts have access to the extracts which is necessary to perform the analyses.

**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.**

All users are trained in proper handling of PII, study procedures to protect the data, and incident reporting guidelines. For all Abt employees, they take the General Security Awareness and CITI human subjects training. For all non-Abt employees, they review the public AHRQ security awareness and provide an email acknowledgment of completion. They also complete CITI or equivalent human subjects training.

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

In-person and web-based trainings will be held for all system users prior to any data collection. Training will include collecting and maintaining all PII for scheduling purposes, secure transmission at appropriate levels for that PII, and use of EMR PII to create an encrypted unique client identifier (EUCI)/ There will be strong emphasis on the study prohibition of recording and removing any of the PII of patients used to create the EUCI.

**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.**

General Records Schedule (GRS) 3.2. Item 010, Disposition Authority: DAA-GRS-2013-0006-0001. Destroy 1 year(s) after system is superseded by a new iteration or when no longer needed for agency/IT administrative purposes to ensure a continuity of security controls throughout the life of the system.

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

The system developed to support this project has been designed using the National Institute of Standards and Technology Special Publication 800-53 revision 4. The system has defined policies and procedures for account creation and system management. To protect the files, Microsoft Windows Active Directory controls folder permissions through discretionary access control. User accounts have strong password requirements, and all mobile devices that store the data utilize FIPS140-2 full device encryption. The data are physically stored within facilities that have keycard access and the servers are within another keycard access server room. The facility has cameras, alarms, and fire suppression systems.

Lastly, the PII is stripped prior to transmitting it outside of the initial data collection device. The PII is converted into a 1-way hash. The PII is then stripped away and the hash, along with the research associates.