

Privacy Impact Assessment Form

v 1.21

Status Form Number Form Date

Question

Answer

1 OPDIV:

2 PIA Unique Identifier:

2a Name:

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

- General Support System (GSS)
 Major Application
 Minor Application (stand-alone)
 Minor Application (child)
 Electronic Information Collection
 Unknown

3a Identify the Enterprise Performance Lifecycle Phase of the system.

3b Is this a FISMA-Reportable system?

- Yes
 No

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

- Yes
 No

5 Identify the operator.

- Agency
 Contractor

6 Point of Contact (POC):

POC Title
 POC Name
 POC Organization
 POC Email
 POC Phone

7 Is this a new or existing system?

- New
 Existing

8 Does the system have Security Authorization (SA)?

- Yes
 No

8b Planned Date of Security Authorization

 Not Applicable

8c	Briefly explain why security authorization is not required	N/A
10	Describe in further detail any changes to the system that have occurred since the last PIA.	New information collection
11	Describe the purpose of the system.	<p>The Antiretroviral Improvement among Medicaid Enrollees (AIMS) study is a cluster-randomized controlled Data-to-Care intervention with targeted provider- and patient-level support. The targeted population are persons with HIV who are enrolled in Virginia Medicaid and who have either never filled an (Antiretroviral) ARV prescription or who are > 30 to < 90 days late filling their ARV prescription. Data will be collected to determine study eligibility, to conduct patient- and provider-level interventions and to determine study outcomes.</p>
12	Describe the type of information the system will collect, maintain (store), or share. (Subsequent questions will identify if this information is PII and ask about the specific data elements.)	<p>Virginia Medicaid: Contains demographics and medical diagnosis, procedure and pharmacy claims for Virginia Medicaid enrollees. Virginia Medicaid also includes identifying information such as; Social Security Number (SSN), Name, Date of Birth (DOB), Phone numbers, and Mailing Address. Data will be securely transferred from Department of Medical Assistance Services (DMAS--VA Medicaid) to the Virginia Department of Health (VDH) server where they will be matched to the VDH Care Marker data to determine study eligibility. No PII will be accessed outside of the DMAS or VDH servers and none will be sent to CDC.</p> <p>VDH Care Marker database: Contains information on all people with HIV in Virginia and includes HIV surveillance data (e.g., HIV viral load), care reports for persons receiving (AIDS Drug Assistance Program) ADAP benefits, vital status, demographics and some care utilization data (e.g., dates of medical visit, ARV prescriptions). Data will be matched to the Medicaid data to determine study eligibility. No PII will be accessed outside of the DMAS or VDH servers and none will be sent to CDC.</p> <p>Phase I and Phase II patient-level semi-structured interviews: A one-time Phase I and/or Phase II semi-structured interview will be administered for participants of the patient-level intervention. All data from the Phase I and II interviews will be entered directly into VDH's REDCap system, a system with its own approved PIA.</p> <p>Clinician consultation: A one-time peer-to-peer clinician consultation will be administered for the provider-level intervention. All data from the consultation will be entered into VDH REDCap, a system with a currently approved PIA.</p> <p>PositiveLinks mobile app: Data from the app (e.g., participants' response rates for daily queries about medication, mood and stress, posts to the community message board) will be downloaded through the app's administrative web portal.</p>

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

Virginia Commonwealth University (VCU -- grantee) will construct de-identified analytic datasets. All study data will be de-identified and all PII elements will be removed from the original data, and a new de-identified analytic dataset will be created in accordance with HIPAA regulations and 45 CFR 164.514. Only de-identified analytic datasets will be sent to CDC. CDC will not be able to re-identify participants in the de-identified analytic dataset. These datasets will be sent to CDC through the CDC Secure Data Network.

Two databases used in this study (Virginia Medicaid and Virginia Care Marker) routinely contain personally identifiable information. These existing data are not collected for the purpose of this study but are routinely collected by DMAS for payment of administrative insurance claims and VDH for HIV surveillance. The study will use identifiable information to: link the VA Medicaid and Care Marker databases (e.g., name, social security number, phone number, date of birth, mailing address); to identify persons for intervention (e.g., identifiable data will be used to determine persons late filling ARV prescriptions); and to facilitate the collection of response data (e.g., names, telephone numbers and mailing address will be used to contact participants for patient- and provider-level interventions, name of participants' Medicaid Managed Care Organization will be used to refer participants to appropriate resources). These identifiable data will remain on the DMAS and VDH servers (which routinely contain this information)—no identifiable data will be downloaded to VCU servers and none will be sent to CDC.

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

Yes
 No

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

<input checked="" type="checkbox"/> Social Security Number	<input checked="" type="checkbox"/> Date of Birth
<input checked="" type="checkbox"/> Name	<input type="checkbox"/> Photographic Identifiers
<input type="checkbox"/> Driver's License Number	<input type="checkbox"/> Biometric Identifiers
<input type="checkbox"/> Mother's Maiden Name	<input type="checkbox"/> Vehicle Identifiers
<input type="checkbox"/> E-Mail Address	<input checked="" type="checkbox"/> Mailing Address
<input checked="" type="checkbox"/> Phone Numbers	<input type="checkbox"/> Medical Records Number
<input type="checkbox"/> Medical Notes	<input type="checkbox"/> Financial Account Info
<input type="checkbox"/> Certificates	<input type="checkbox"/> Legal Documents
<input type="checkbox"/> Education Records	<input type="checkbox"/> Device Identifiers
<input type="checkbox"/> Military Status	<input type="checkbox"/> Employment Status
<input type="checkbox"/> Foreign Activities	<input type="checkbox"/> Passport Number
<input type="checkbox"/> Taxpayer ID	<input type="text" value="Other..."/>
<input type="text" value="Other..."/>	<input type="text" value="Other..."/>
<input type="text" value="Other..."/>	<input type="text" value="Other..."/>

16	Indicate the categories of individuals about whom PII is collected, maintained or shared. <input type="checkbox"/> Employees <input type="checkbox"/> Public Citizens <input type="checkbox"/> Business Partners/Contacts (Federal, state, local agencies) <input type="checkbox"/> Vendors/Suppliers/Contractors <input checked="" type="checkbox"/> Patients Other <input type="text"/>
17	How many individuals' PII is in the system? <input type="text" value="500-4,999"/>
18	For what primary purpose is the PII used? <input type="text" value="To determine participant eligibility (e.g., identifiable data will be used to determine persons late filling ARV prescriptions and to link the DMAS and VDH Care Marker datasets)."/>
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research) <input type="text" value="To facilitate the collection of response data (e.g., names and telephone numbers will be used to contact participants for patient- and provider-level interventions, name of participants' Medicaid Managed Care Organization will be used to refer participants to appropriate resources)."/>
20	Describe the function of the SSN. <input type="text" value="A validated HIV case identification algorithm will be applied to the Virginia Medicaid database to identify persons with HIV who have either never filled an ARV prescription or have not filled an ARV prescription within >30 to < 90 days of the expected fill date. These individuals will be considered preliminarily eligible for study participation. Deterministic and probabilistic methods will be used to match this list with the Virginia Care Markers databases. Social security number along with other PII (e.g., name, date of birth, address) will be used to make the match between the databases. Individuals that are matched across the two databases (indicating that the persons are both enrolled in Medicaid and confirmed HIV positive) are eligible for study participation."/>
20a	Cite the legal authority to use the SSN. <input aspe.hhs.gov="" https:="" personal-privacy-information-society="" report="" restrictions-use-ssn"="" type="text" value="Section 1211 of the Tax Reform Act of 1976: https://aspe.hhs.gov/report/personal-privacy-information-society/restrictions-use-ssn"/>
21	Identify legal authorities governing information use and disclosure specific to the system and program. <input type="text" value="Consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this research because this research is funded or supported by CDC and the following are true: the research involves Human Subjects as defined by 45 CFR Part 46; the research involves information about an individual for which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. The Certificate of Confidentiality protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information; the research team cannot be forced (e.g., court subpoena) to disclose identifying information from study participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level."/>
22	Are records on the system retrieved by one or more PII data elements? <input checked="" type="radio"/> Yes <input type="radio"/> No

22a Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or identify if a SORN is being developed.

Published: Privacy Act System Notice 09-20-0136: "Epidemiology and Public Health System of Records Notice (SORN) for the COVID-19 Response"

Published: []

Published: []

In Progress

23 Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

- In-Person
- Hard Copy: Mail/Fax
- Email
- Online
- Other

Government Sources

- Within the OPDIV
- Other HHS OPDIV
- State/Local/Tribal
- Foreign
- Other Federal Entities
- Other

Non-Government Sources

- Members of the Public
- Commercial Data Broker
- Public Media/Internet
- Private Sector
- Other

23a Identify the OMB information collection approval number and expiration date.

Pending

24 Is the PII shared with other organizations?

Yes

No

24a Identify with whom the PII is shared or disclosed and for what purpose.

- Within HHS
- Other Federal Agency/Agencies
- State or Local Agency/Agencies
- Private Sector

All PII will remain within the DMAS and VDH servers to

VCU will have access to PII on the DMAS and VDH servers to

24b Describe any agreements in place that authorizes the information sharing or disclosure (e.g. Computer Matching Agreement, Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).

Virginia Commonwealth University (VCU) has been given DMAS and VDH affiliate status which allows them to access the Virginia Medicaid and VDH Care Marker databases on the VDH and DMAS servers, respectively. Data necessary for the study will be placed in study specific files on the secure DMAS and VDH servers by DMAS and VDH personnel. VCU will only have access to the study files. VCU has access to these data through study-specific amendments to existing cross-agency and cross-institutional data use agreements.

<p>24c Describe the procedures for accounting for disclosures</p>	<p>Only de-identified analytic datasets will be transferred and downloaded onto Virginia Commonwealth University (VCU) servers. VCU personnel will not be able to re-identify participants in the de-identified analytic dataset. The dataset will be protected from improper use and disclosure through use of university-wide data security standards as outlined in the VCU Research Data Ownership, Retention, Access, and Security policy. Only authorized persons at VCU will have access to these data.</p>
<p>25 Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.</p>	<p>The Virginia Medicaid and Care Marker databases are existing data that are not collected for the purpose of this study but are routinely collected by DMAS and VDH for payment of administrative insurance claims and HIV surveillance. For the patient- and provider-level intervention, participants will be informed that participation is voluntary, and they are at liberty not to answer any questions and may end participation at any time. We will indicate that participation is voluntary and will not affect provision of any public benefits. Participants will be informed that there is no monetary incentive to participate and will be given as much time as necessary to decide whether to participate.</p>
<p>26 Is the submission of PII by individuals voluntary or mandatory?</p>	<p><input checked="" type="radio"/> Voluntary <input type="radio"/> Mandatory</p>
<p>27 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.</p>	<p>The Virginia Medicaid and Care Marker databases are existing data that are not collected for the purpose of this study but are routinely collected by Virginia Department of Medical Assistance Services (DMAS) and Virginia Department of Health (VDH) for payment of administrative insurance claims and HIV surveillance. Participation in the patient- and provider-level interventions is voluntary.</p>
<p>28 Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained.</p>	<p>The Virginia Medicaid and Care Marker databases are existing data that are not collected for the purpose of this study but are routinely collected by DMAS and VDH for payment of administrative insurance claims and HIV surveillance. Virginia Medicaid and Care Marker already has obtained consent from the individuals.</p>
<p>29 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. If no process exists, explain why not.</p>	<p>The Virginia Medicaid and Care Marker databases are existing data that are not collected for the purpose of this study but are routinely collected by DMAS and VDH for payment of administrative insurance claims and HIV surveillance, therefore, an individual with concerns may contact Virginia Medicaid and Care Marker for this process.</p>
<p>30 Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. If no processes are in place, explain why not.</p>	<p>The Virginia Medicaid and Care Marker databases are existing data that are not collected for the purpose of this study but are routinely collected by DMAS and VDH for payment of administrative insurance claims and HIV surveillance, therefore Virginia Medicaid and Care Marker ensure their data.</p>

31	Identify who will have access to the PII in the system and the reason why they require access.	<input type="checkbox"/> Users <input type="checkbox"/> Administrators <input type="checkbox"/> Developers <input type="checkbox"/> Contractors <input checked="" type="checkbox"/> Others	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> VCU will have access to PII on the DMAS and VDH servers to determine
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The VCU Statistician and Data Manager will have access to the PII to determine study eligibility. DMAS and VDH staff access to PII is determined by DMAS and VDH agency policy.	
33	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.	Virginia Commonwealth University (VCU) has been given DMAS and VDH affiliate status which allows them to access the Virginia Medicaid and VDH Care Marker databases on the VDH and DMAS servers, respectively. Data necessary for the study will be placed in study specific files on the secure DMAS and VDH servers by DMAS and VDH personnel. VCU will only have access to the study files. DMAS and VDH staff access to PII is determined by DMAS and VDH agency policy.	
34	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.	CDC study staff will complete the computer-based Scientific Integrity and Quality Training research ethics and compliance training. CDC study staff will also complete the Information Security Awareness Training annually.	
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Virginia Commonwealth University researchers are trained in and adhere to the "Responsible Conduct of Research", (https://research.vcu.edu/responsible_conduct/data_collection.htm) and "Research Data Ownership, Retention, Access, and Security Policy Statement", (https://policy.vcu.edu/universitywide-policies/policies/research-data-ownership-retention-access-and-security.html) to ensure the general security and privacy of research respondents.	
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
37	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.	No identifiable data will be sent to CDC. Virginia Commonwealth University will construct de-identified analytic datasets. All study data will be de-identified and all PII elements will be removed from the original data, and a new de-identified analytic dataset will be created in accordance with HIPAA regulations and 45 CFR 164.514. Only de-identified analytic datasets will be sent to CDC. CDC will not be able to re-identify participants in the de-identified analytic dataset.	

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

Administrative Controls: No identifiable data will be sent to CDC. Virginia Commonwealth University will construct de-identified analytic datasets. All study data will be de-identified and all PII elements will be removed from the original data. This information is only available to project staff. These data can only be linked with effort because they are stored in separate data files.

Technical Controls: The data collection contractor has several security procedures in place to safeguard data. All electronic data will be stored on secured servers and will be accessible only to staff directly involved in the project. Also, all contractor staff involved with the project will be required to sign a Data Collector Confidentiality Agreement, which is a statement of personal commitment to guard the confidentiality of data.

Physical Controls: No identifiable data will be stored at Virginia Commonwealth University. The data collection contractor will remotely access data at individual workstations physically located in an office building with various levels of physical access controls, including security guards, card access, and locking department and office doors which are locked when vacant. Only authorized project personnel will have access to computer output.

REVIEWER QUESTIONS: The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

Reviewer Questions		Answer
1	Are the questions on the PIA answered correctly, accurately, and completely?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes	<input type="text"/>	
2	Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes	<input type="text"/>	
3	Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes	<input type="text"/>	
4	Does the PIA appropriately describe the PII quality and integrity of the data?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes	<input type="text"/>	
5	Is this a candidate for PII minimization?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes	<input type="text"/>	

Reviewer Questions		Answer	
6	Does the PIA accurately identify data retention procedures and records retention schedules?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
7	Are the individuals whose PII is in the system provided appropriate participation?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
8	Does the PIA raise any concerns about the security of the PII?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
10	Is the PII appropriately limited for use internally and with third parties?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
12	Were any changes made to the system because of the completion of this PIA?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
General Comments	<input type="text"/>		
OPDIV Senior Official for Privacy Signature	<input type="text"/>	HHS Senior Agency Official for Privacy	<input type="text"/>