

Privacy Impact Assessment Form

v 1.21

Status Form Number Form Date

Question

Answer

1 OPDIV:

CDC

2 PIA Unique Identifier:

0920-19BG

2a Name:

Web-based Approaches to Reach Black or African American and

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.

Initiation

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	Not applicable.
10	Describe in further detail any changes to the system that have occurred since the last PIA.	Not applicable.
11	Describe the purpose of the system.	The purpose of this information collection is to assess the effectiveness of mailing out rapid Human Immunodeficiency Virus (HIV) self-testing kits and providing access to Internet-based prevention mobile applications and websites as a public health strategy for increasing Black and Hispanic/Latino men who have sex with men (MSM) linkage to appropriate prevention and care services.
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.)	Personally identifiable information (PII) including name, E-mail Address, Phone Number, Mailing Address, Military Status, Date of Birth, Employment Status, Age, Race/Ethnicity, City/Zip Code, Sex, Sex at Birth, Sexual Orientation, Education Level, and Annual Income Information will be collected. Respondents also will receive unique identification non-identifiable codes.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	All collected, maintained, and shared PII will be used to mail HIV testing kits and ensure receipt of those kits. PII will also allow study staff and partners to contact study participants for video counseling and other supportive services.
14	Does the system collect, maintain, use or share PII?	<input checked="" type="radio"/> Yes <input type="radio"/> No
15	Indicate the type of PII that the system will collect or maintain.	<input 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 checked="" 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 checked="" type="checkbox"/> Military Status <input checked="" type="checkbox"/> Employment Status <input type="checkbox"/> Foreign Activities <input type="checkbox"/> Passport Number <input type="checkbox"/> Taxpayer ID <input type="text" value="City/Zip Code"/> <input type="text" value="Age"/> <input type="text" value="Sex/Sex at Birth"/> <input type="text" value="Race/Ethnicity"/> <input type="text" value="Sexual Orientation, Education Level, Annual income Information"/>

16	Indicate the categories of individuals about whom PII is collected, maintained or shared. <input type="checkbox"/> Employees <input checked="" type="checkbox"/> Public Citizens <input type="checkbox"/> Business Partners/Contacts (Federal, state, local agencies) <input type="checkbox"/> Vendors/Suppliers/Contractors <input 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="PII data will be used to determine eligibility for this study."/>
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research) <input type="text" value="PII data also will be used to maintain contact with participants once enrolled in the study, mail out HIV testing kits, schedule and conduct follow-up HIV video counseling, and initiate participants engagement with the health Mpowerment website."/>
20	Describe the function of the SSN. <input type="text" value="Not applicable."/>
20a	Cite the legal authority to use the SSN. <input type="text" value="Not applicable."/>
21	Identify legal authorities governing information use and disclosure specific to the system and program. <input (42="" 241);="" 242="" 304,="" 306="" 308(d)="" activities="" and="" assurances="" authority="" b,="" confidentiality="" data="" discuss="" for="" health="" investigation,\"="" k,="" m(d))."="" maintain="" of="" provide="" related="" research="" sections="" to="" type="text" u.s.c.="" value="Public Health Service Act, Section 301, \" which=""/>
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: <input health"="" in="" of="" records="" subjects="" type="text" value="SORN 09-20-0160, \"/> Published: <input type="text"/> Published: <input type="text"/> <input type="checkbox"/> 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.

To be determined.

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 PII will be shared or disclosed in acco
- Private Sector PII will be shared or disclosed with other study sites hosted by

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)).

An MOU, signed by Emory University, the University of North Carolina--Chapel Hill, and the University of Michigan, authorizes data and information sharing for the purposes of this study.

24c Describe the procedures for accounting for disclosures

Not applicable.

<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>At the beginning of the study eligible participants will be asked to review and electronically sign a study consent form that informs participants that personal identifying information will be collected and every effort will be made to keep this information confidential. The consent form will include an explanation of the study, risks and benefits of participation, duration of participation, contact information for individuals who can answer questions about the research study regarding participant rights and protections, the voluntary nature of participation, and the right to withdraw without penalty. Participant are provided with information to contact study staff if clarification is needed regarding consent processes.</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>Participants can opt out of all PII questions that are not eligibility related. Also, participants can opt out of participating in the study altogether or withdraw from the study at any time.</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>All participants will be allowed to track study progress and to correspond with study management if any changes are made to the system. They will be able to contact the Emory study team or the Emory Institutional Review Board (IRB).</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>Study participants will be provided contact information and instruction to contact either the grantee principal investigators as well as the Emory human subjects staff if they have any questions about their rights as a participant or concerns that their PII may have been inappropriately obtained, used, or disclosed:</p> <p>Emory IRB 404-712-0720 or 877-503-9797 irb@emory.edu</p> <p>Emory Study Team 404-727-4340 iSTAMP@emory.edu</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>Participants will be able to update PII at each interval of study participation when filling out surveys for data collection purposes.</p>	
<p>31 Identify who will have access to the PII in the system and the reason why they require access.</p>	<p><input type="checkbox"/> Users</p> <p><input checked="" type="checkbox"/> Administrators</p> <p><input type="checkbox"/> Developers</p> <p><input type="checkbox"/> Contractors</p> <p><input checked="" type="checkbox"/> Others</p>	<p></p> <p>Study site administrators will have access to PII to contact study</p> <p></p> <p></p> <p>Study staff assisting administrators may also have limited access to PII in</p>

32 Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The ability to designate specific roles in Emory's digital study software allows users to control permissions and accessibility to participant information. Staff accessing the system will be limited by which PII data is necessary to perform the duties of their position. Users also are limited to a reporting-only role, allowing for study oversight through real-time aggregate reporting, but no access to protected health information (PHI). The Centers for Disease Control and Prevention (CDC) lacks access to these data.
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.	Access to Sensitive PII will be restricted to individuals trained in human subject protections. PII is collected for a specific and identifiable purpose with access restricted to specific job tasks and individuals who perform those tasks. Assigned user permissions will be determined by their roles to perform different actions and need to view PII.
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.	All research personnel employed by Emory and subcontractors under this contract will have completed Collaborative Institutional Training Initiative (CITI) training before they are permitted to participate in research or view PII. All study staff will be trained on relevant study procedures prior to interacting with participants involved in study activities.
35 Describe training system users receive (above and beyond general security and privacy awareness training).	Emory researchers and study staff will participate in internal training on study instruments, procedures, and reporting regulations, which includes privacy awareness and confidentiality training. Graduate research assistants also must sign a code of conduct to ensure participants' safety and privacy.
36 Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	<input type="radio"/> Yes <input checked="" 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.	Records are retained and disposed of in accordance with the CDC Records Control Schedule 04-4-22 Family of HIV Surveys, Division of HIV/AIDS Prevention/Surveillance and Epidemiology, (N1-442-02-3-4, Item 1) and Division of HIV/AIDS Prevention/Surveillance and Epidemiology, (N1-442-02-3, Item 1). Record copy of study reports are maintained in agency records from two to three years in accordance with retention schedules. Source documents for computer are disposed of when no longer needed by program officials. Personal identifiers may be deleted from records when no longer needed in the study as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include erasing computer disks or tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. Cut off closed grant, contract, or cooperative agreement files at the end of the calendar year in which the project ends or a final report is written and destroy six years after cut off.

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

Physical
 All printed records will be securely stored in locked file cabinets within locked offices and monitored during access. No names or other identifying information appear on data documents or in data files, as the re-contact information will be stored separately. Only designated staff will have access to the data.

Technical
 PII is stored in a database that provides staff with the minimum amount of data needed to perform tasks associated with their position. The application securely maintains participant information behind a firewall rendered over a Secure Sockets Layer (SSL) certificate for administrator-only access. All passwords are stored encrypted within the database, which also uses database level encryption to prevent information copying from one database to another. Web application also uses an automatic logout feature after a certain period of inactivity.

Administrative
 All respondents will receive unique identification non-identifiable codes, which will be stored separately from PII on a password protected computer. These codes will be used as the de-identified data set that will later be shared with CDC. CDC does not have access to the database. All staff collecting data will participate in a training that will review protections for privacy and confidentiality of all data, including PII. Only Principal Investigators may handle requests to examine data collected during this study.

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 Questions		Answer	
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"/>		
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"/>