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Privacy Impact Assessment Form

v 1.21

Status | Form Number: 00000 | Form Date: 11/30/17

	Question	Answer
1	OPDIV:	CDC/NCHHSTP/DHAP
2	PIA Unique Identifier:	0920-17AX
2a	Name:	Mobile Messaging Intervention to Present New HIV Prevention O
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: Project Officer POC Name: Gordon Mansergh, PhD POC Organization: DHPIRS/PRB POC Email: GCM2@cdc.gov POC Phone: 404.639.6135
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

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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.	N/A
11	Describe the purpose of the system.	The purpose of this research study is to test the efficacy of a smartphone-based sexual health and HIV prevention messaging intervention for men who have sex with men (MSM), known as M3 through a randomized controlled trial. The study will evaluate whether M3 smartphone-based intervention is an effective HIV-prevention strategy by assessing whether exposure to the messaging intervention results in improvements in men's self-reported sexual health and HIV prevention behaviors, attitudes, and beliefs.
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.)	The information collected will include: pre-exposure prophylaxis (PrEP); antiretroviral (ARV) usage; condom efficacy; and frequency of HIV/STD testing. Names, email addresses and/or telephone numbers will be collected and stored. Although Emory will conduct the data collection the instrument is developed and owned by CDC. The participant/ unique identification number will be automatically generated once respondent log on to complete the survey. Data will be sent to CDC in a de-identified and de-linked format. No PII will be transmitted to CDC.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	M3 is a mobile-messaging intervention application. Information collected will include several types of sensitive information—including participant HIV status, ART and PrEP use, HIV and STI testing, and sex behaviors—from men who have sex with men (MSM)M3. The initial steps of the data collection process will involve participant screening and consent to complete a brief online questionnaire, which will require eligible participants to provide contact information (name, phone number and email address). Data will be collected through an online behavioral assessment, to be completed in 3-month intervals over the 9 month study period. All participants will be assigned a unique identification number for the study, so that each person's data will be identified only by study participant ID. Identification data will be maintained by Emory for purposes of follow-up with participants. CDC will not have access to PII maintained by Emory.
14	Does the system collect, maintain, use or share **PII**?	(•) Yes ( ) No

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15	Indicate the type of PII that the system will collect or maintain.	☐ Social Security Number ☒ Name ☐ Driver's License Number ☐ Mother's Maiden Name ☒ E-Mail Address ☒ Phone Numbers ☐ Medical Notes ☐ Certificates ☐ Education Records ☐ Military Status ☐ Foreign Activities ☐ Taxpayer ID Other... Other...	☐ Date of Birth ☐ Photographic Identifiers ☐ Biometric Identifiers ☐ Vehicle Identifiers ☒ Mailing Address ☐ Medical Records Number ☐ Financial Account Info ☐ Legal Documents ☐ Device Identifiers ☐ Employment Status ☐ Passport Number Name, phone number, Email and address collected are not included in the Emory or CDC data sets. They are kept separate from data at all times, and are never linked to the data. Other... Other...
16	Indicate the categories of individuals about whom PII is collected, maintained or shared.	☐ Employees ☒ Public Citizens ☐ Business Partners/Contacts (Federal, state, local agencies) ☐ Vendors/Suppliers/Contractors ☐ Patients Other	
17	How many individuals' PII is in the system?	500-4,999	
18	For what primary purpose is the PII used?	The primary purpose for the PII is to follow-up with participants on assessment intervals and provide remuneration for participation.	
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)		
20	Describe the function of the SSN.	N/A	
20a	Cite the **legal authority** to use the SSN.	N/A	
21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	Public Health Service Act, Title III, Section 301	
22	Are records on the system retrieved by one or more PII data elements?	◉ Yes ○ No	

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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:	SORN 09-20-0160, "Records of Subjects in Health
		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.	0920-17AX	
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	
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)).	N/A	
24c	Describe the procedures for accounting for disclosures	TBD	

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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.	Users are informed that their personal information will be collected prior to their volunteering to participate in the study.
26	Is the submission of PII by individuals voluntary or mandatory?	(•) Voluntary ( ) Mandatory
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.	Participants must consent to being a part of the study and are informed on the consent document that they can opt out at any time. However, failure to provide the PII might impact their ability to continue participation.
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.	When majors changes occur, participants will be notified by email or phone/text.
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.	Individuals should reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. In the event of a suspected data breach, the reporting jurisdiction must report the incident to the Emory University's with complete information detailing the nature of the suspected breach. Emory has procedures in place to respond to a breach and is required to notify the Project Officer who reports the suspected incident to NCHHSTP's Information Security Office and works with the Emory until the matter has been resolved. If, however, the individual believes their PII is inaccurate, this should be reported to Emory university for further investigation. CDC does not receive or have access to the individual``s PII.
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.	Data collection requirements as a whole are reviewed by CDC and CDC-funded grantees annually. All PII data are maintained at the local level by CDC-funded grantees and are not shared with CDC. Review processes may vary as each health department grantee will have jurisdiction-specific guidelines in place for conducting internal reviews of PII in the system.
31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users ☐ Administrators ☐ Developers ☐ Contractors ☒ Others — Only study staff at Emory University (the cooperative agreement awardee)
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Access to PII within the SMART system is based on specific staff role (recruitment, retention, study coordination) based on the established operational protocol for the research project. CDC never has access to the SMART system that is based and managed locally at Emory for all study sites.

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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.	The SMART system retrieves only the minimum amount of information required for follow-up data collection with study participants who have agreed/consented to participate in the study. Only the study coordinator, recruitment coordinator, retention coordinator, and SMART network administrators have access to the SMART system containing 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.	Emory study staff have undergone training by CITIprogram on "Human Subjects Research — Social-Behavioral-Educational" (see www.citiprogram.org), a training that covers privacy and confidentiality, related federal regulations, and research ethics.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Project staff are required to take training conducted by CITIprogram titled "Information Privacy and Security — Information Security Module", which covers Information Security, securing identity, safer email use, and related regulations. Emory research staff are also informed of and required by the Emory IRB system to implement IT policies and standards in compliance with the Gramm-Leach-Bliley Act, which protects personal identifying information such as names, addresses, and other sensitive information. Emory University study leadership has provided a multi-day training -- to all personnel on this specific project across the 3 sites -- on data security, confidentiality, ethical issues, and privacy of persons in the public and study participants, among other critical research issues.
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	○ Yes ◉ 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.

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38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Physical: Staff must gain access to the building through a keycard. All records are stored in locked offices and in locked filing cabinets. To access any computer linked to Emory's secured data server, one must have Emory log-in credentials. Administrative: Limited to study staff only at Emory. Technical: Emory's study staff gains access to Emory's SMART system by proving their user-id and password. SMART is stored on Emory's secured network drive protected by a firewall and requiring special access permission for staff through Emory's IT department.

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?	◯ Yes ◯ No
Reviewer Notes		
2	Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?	◯ Yes ◯ No
Reviewer Notes		
3	Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors?	◯ Yes ◯ No
Reviewer Notes		
4	Does the PIA appropriately describe the PII quality and integrity of the data?	◯ Yes ◯ No
Reviewer Notes		
5	Is this a candidate for PII minimization?	◯ Yes ◯ No
Reviewer Notes		
6	Does the PIA accurately identify data retention procedures and records retention schedules?	◯ Yes ◯ No
Reviewer Notes		
7	Are the individuals whose PII is in the system provided appropriate participation?	◯ Yes ◯ No
Reviewer Notes		

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	Reviewer Questions	Answer
8	Does the PIA raise any concerns about the security of the PII?	◯ Yes ◯ No
Reviewer Notes		
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	◯ Yes ◯ No
Reviewer Notes		
10	Is the PII appropriately limited for use internally and with third parties?	◯ Yes ◯ No
Reviewer Notes		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	◯ Yes ◯ No
Reviewer Notes		
12	Were any changes made to the system because of the completion of this PIA?	◯ Yes ◯ No
Reviewer Notes		

General Comments	

OPDIV Senior Official for Privacy Signature	Beverly E. Walker -S Digitally signed by Beverly E. Walker -S Date: 2017.11.30 23:30:47 -05'00'	HHS Senior Agency Official for Privacy	