U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 8/25/21

Title:	Project DETECT 2.0 Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence
Project Id:	0900f3eb81d78c3c
Accession #:	NCHHSTP-BCSB-7/12/21-78c3c
Project Contact:	Kevin Delaney
Organization:	NCHHSTP/DHAP/BCSB
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	07/19/2021
Estimated Completion Date:	09/30/2024
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1100

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Research that involves de-identified/unlinkable data or biospecimens, but not involving FDA investigational products *45 CFR 46.102(e)*	7/16/21	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		7/20/21	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

ICRO: **PRA Applies**	OMB Approval date: 1/16/19 OMB Expiration date: 1/31/22	7/20/21	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	07/30/2021
Determination Start Date:	07/12/21
Description:	The purpose of this request is to amend the original project determination (PD) which was approved on 08/18/2015 before STARS and is being entered into STARS for the first time. The original PD received an HSR determination that the activity is research involving human subjects but CDC involvement does not constitute engagement in human subject research and that has not changed. The PRA does apply. An ICR has been submitted to extend the current OMB approval (OMB 0920-1100, Exp. January 31, 2022) and to add an additional data collection site. The ICR packet was submitted and the 60-day FRN was published on (July 12, 2021; (Docket #CDC-2021-0066). This evaluation of new HIV testing technologies in clinical settings with high HIV incidence (DETECT 2.0) is a 3-year research project to assess the relative performance of new and developing POC HIV tests, particularly among persons who: (a) present diagnostic challenges, including those exposed to HIV PrEP; (b) those with very recent HIV infection (before the development of a mature antibody response); and (c) those achieving viral suppression before developing an antibody response, among others. To achieve this, CDC awarded two recipients to evaluate the differences in sensitivity and specificity of the newest HIV serologic tests, using unprocessed specimens collected from infected individuals who are in the acute or early stages of disease. One recipient is the University of Washington, which participated in the original project since the initial determination; this amendment adds Johns Hopkins University as a site.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The goals of the project are to 1) characterize the performance (sensitivity and specificity) of HIV tests under development and/or new HIV tests for detecting established and early HIV infection at the point of care (POC), relative to each other and to currently used gold standard, non-POC tests which are processed in a centralized laboratory rather than at point of care and 2) identify behavioral and clinical predictors of early HIV infection

Objective:	The overall project objectives include: 1) Developing and implementing recruitment strategies and procedures to: (a) identify appropriate study participants to evaluate the differences in sensitivity (including acute HIV infection sensitivity) and specificity of the newest HIV tests in real time using fresh whole blood and oral fluid specimens; and (b) compare results to the currently recommended CDC laboratory algorithm (12). Patients with exposure to either early ART or PrEP should be oversampled to evaluate HIV test performance in these populations as well. 2) Evaluate the seroconversion sensitivity of the newest HIV tests through serial follow-up of study participants with discordant baseline test results. 3) Evaluate the diagnostic and clinical performance of nucleic acid (molecular) tests to determine the applicability of this technology for use in a variety of clinical and POC settings. 4) Collect matched demographic, behavioral and clinical data from participants to assess the impact of these factors on HIV test performance, including the use of behavioral and clinical data to categorize the timing of exposure for those with newly diagnosed infection. 5) Develop panels of specimens with accompanying demographic, clinical and behavioral data for evaluations of laboratory-based HIV tests.
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	No
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Yes
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Secondary Data or Specimen Analysis ; Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials
Target Populations to be Included/Represented:	General US Population ; Asian ; Black or African American ; Hispanic or Latino ; Native Hawaiian or Other Pacific Islander - Men who have sex with men; persons who inject drugs ; White ; Female ; Male ; Transgender ; Adult 18-24 years ; Other - Men who have sex with men; persons who inject drugs
Tags/Keywords:	HIV Infections ; HIV Seropositivity ; Acute Disease
CDC's Role:	CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is providing funding ; CDC provides technical assistance but does not specifically request or approve study design or data collection
Method Categories:	Analytic Services (can be data/specimen TA for non-research,research,investigations); Method/Device Evaluation; Prospective Cohort Study; Randomized Controlled Trial; Secondary Data Analysis; Secondary Specimen Analysis
	For those who consent to testing at the clinics or emergency department, basic demographic information, HIV testing history, and HIV risk in the prior 3 months will be extracted from data routinely collected from all clinic patients regardless of study participation. These data will be used to categorize patients into high or low risk groups. Patients classified as high risk#males who have reported any male sex partners (MSM) in the past 12 months, transgender women, minorities, and persons who inject drugs (PWIDs)# will be immediately enrolled in Phase 1 of the study, for which specimens are collected for additional testing with novel HIV testing

Methods:

technologies. Those categorized as low risk (i.e., all other patients) will be offered the current standard of care for HIV testing at the clinical site. If individuals receiving standard of care testing receive a test result indicating HIV infection, or have been referred to the study because of a positive test result, they will also be offered the opportunity to enroll in Phase 1 of the study, with specimen collection for testing with the novel HIV tests. Phase 1 participants who have discordant results when tested with the novel testing technologies will be eligible for Phase 2 of the study, involving serial follow-up to resolve the discrepancies observed in Phase 1. The respondent universe for Project DETECT 2.0 will be persons who present to Seattle- and Baltimore-area clinics and Johns Hopkins emergency department who are at high risk for HIV infection or have been diagnosed with established or early HIV infection. The following groups will be approached for participation through convenience sampling if they are 18 years of age or older and able to complete the computer-assisted self-interview in English: 1) Persons who present to the PHSKC STD Clinic, Johns Hopkins Infectious Diseases Clinic, Baltimore City STD Clinic, the Johns Hopkins Emergency Department (ED), seeking services and are identified as being at high risk of HIV infection based on their responses to a routinely used clinic intake questionnaire (males who reported any male sex partner in the past 12 months, transgender women, minorities, and PWIDs), 2) Persons who test antibody-positive through routine HIV testing at the PHSKC STD clinic or other participating Seattle-area clinics, Johns Hopkins Infectious Diseases Clinic, Baltimore City STD Clinic, the Johns Hopkins Emergency Department (ED), 3) Persons who self-report their HIV-positive status when seeking other services from the PHSKC STD Clinic, Johns Hopkins Infectious Diseases Clinic, Baltimore City STD Clinic, the Johns Hopkins Emergency Department (ED), 4) Persons who tested HIV-antibody positive at another clinical site in Seattle or Baltimore and were referred to participate in the study, and 5) Persons with test results indicative of early HIV infection (defined according to the CDC recommended HIV testing algorithm) who tested at a site in Seattle or Baltimore outside of the PHSKC STD clinic, Johns Hopkins Infectious Diseases Clinic, Baltimore City STD Clinic, the Johns Hopkins Emergency Department (ED), and were referred to participate in the study. CDC investigators will not participate in data collection or have any other interactions with participants. Only de-identified data will be delivered to CDC scientists; CDC will not receive any personally identifiable information. Any individually identifiable information collected by the recipients

Collection of Info, Data or Biospecimen:

The purpose of this study component is to use data routinely collected at the clinics and emergency department to ascertain whether individuals are at low or high risk for HIV to determine eligibility for Phase 1. Study staff will extract socio-demographic, behavioral, medical history, and testing data routinely collected from all patients for the purposes of clinical care, program monitoring and evaluation, and sentinel surveillance. Basic demographic information, HIV testing history, history of HIV prophylaxis and HIV risk in the prior year will be used in real-time to screen patients to identify high- and lower-risk groups. Those categorized as being at high risk based on this information will be enrolled in Phase 1 of the study, and those categorized as being at lower risk will be enrolled in Phase 1 only if they receive a test result indicating HIV infection. UW and JHU will report de-identified STD program data collected during screening to CDC, and for those deemed to be at lower risk, will also report the results of HIV testing conducted using the standard of care HIV test(s). UW and JHU will develop and maintain a system to link participant information extracted from data collected by the Public Health King County STD clinic, Johns Hopkins Infectious Diseases Clinic, Baltimore City STD Clinic, the Johns Hopkins Emergency Department (ED) to those data collected in Phase 1 and Phase 2 of the study, as described below. Phase 1 Phase 1 participants will consist of two groups of clinic patients: those deemed to be at high risk for recent HIV infection based on the screening questionnaire, and those known to be HIV-positive. The latter group is composed of those considered to be at lower risk who test HIV-positive using the standard of care test conducted at the clinic, those who self-report being HIV-infected during routine data collection at the clinic when they seek STD or other services there, and those who are referred to the study because they were identified as having newly diagnosed HIV infections. The last 2 groups are being included to increase the sample size for evaluation of the sensitivity of the tests under investigation. Those consenting to participate in Phase 1 will have anti-coagulated whole blood, oral fluid and dried-blood spot specimens collected for the evaluation of the new HIV screening and diagnostic tests. UW and JHU will use fresh anti-coagulated whole blood and oral fluid specimens to perform up to 7 new HIV tests. Additionally, UW and JHU will follow an algorithm that includes a 4th generation immunoassay, an HIV-1/HIV-2 differentiation test and a nucleic acid test on the entire Phase 1 study population as the reference standard for the evaluation of the new test technology. Finally, UW and JHU will perform a quantitative HIV-1 viral load test for all study participants identified as HIV-infected. All test results (for the new tests under evaluation, testing with the reference standard, and HIV-1 viral load) as well as the short behavioral questionnaire collected from Phase 1 participants will be reported to CDC. Specimens will be collected for storage and future testing from a subset of participants who consent to specimen storage. In the first 3 years of the study, nearly all

	participants consented to specimen storage and future testing. Specimens will be collected from all consenting participants with at least one reactive HIV test for future evaluations of test sensitivity. To evaluate te
Expected Use of Findings/Results:	The purpose of this research is to evaluate the performance of HIV tests under development, and/or newly available HIV tests (compared to a gold standard), for use in point-of-care settings in the United States. Test performance and questionnaire data will be used to inform HIV testing guidelines; provide information to HIV test providers about the appropriate use of different HIV testing technologies in different settings, and for different populations (e.g., for highest risk persons as well as the general population); and inform the choice of test technology and allow these technologies to be tailored to the strategies needed to end the HIV epidemic.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers?	No
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	Yes
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence (Project DETECT 2.0)	PS20-001	2020	3	3322234.00

HSC Review

HSC Attributes

Other - CDC involvement does not constitute engagement in human subject research.	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	
Population - Children	
Population - Minors	
Population - Prisoners	
Population - Pregnant Women	
Population - Emancipated Minors	

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection

Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Johns Hopkins Bloomberg Sch Public Hlth	FWA00000287	01/07/25	Johns Hopkins Medicine IRB #3	02/01/24	PS20-001
U of Washington	FWA00006878	01/29/25	U of Washington IRB #7 - J	01/04/24	PS20-001

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Brian Emerson	07/02/2022				Project Officer	nsy2@cdc.gov	404-718-3492	SPECIAL STUDIES & DIAGNOSTICES TEAM
David Katz	12/27/2021	12/27/2021	12/28/2021		Co-Investigator	dkatz7@uw.edu		U of Washington
Kevin Delaney	12/27/2021	12/27/2021	12/28/2021		Co-Investigator	khd8@cdc.gov	404-639-8630	BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH
Pollyanna Chavez	12/28/2021	12/28/2021	12/28/2021		Project Coordinator	geo5@cdc.gov	404-639-1742	SPECIAL STUDIES & DIAGNOSTICES TEAM
Yuka Manabe	12/27/2021	12/27/2021	12/28/2021		Co-Investigator	ymanabe@jhmi.edu		Johns Hopkins Bloomberg Sch Public Hlth

Data

DMP

Proposed Data Collection Start Date: 9/30/21

Proposed Data Collection End Date: 9/30/24

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL: Not yet available

Data Use Contact: Kevin Delaney

Public Access Justification:	These data are being collected through a Cooperative agreement with our academic partners. The data reported to CDC includes sensitive but deidentified information about HIV risk as well as HIV test results. These data are given formal confidentiality protection locally under 308(d) of the Public Health Service Act. All data release and sharing must be consistent with the confidentiality certificates and assurances under which the data were collected or generated. These data will be pared with stored specimens in a biorepository made available to CDC researchers, and, through Research collaborations or Materials Transfer, to external partners following guidelines developed by the technology transfer office. Where applicable, for data underlying scientific publication, CDC and/or the recipients will make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism.
How Access Will Be Provided for Data:	CDC will develop a Data sharing/analysis proposal template through which the grantees and external partners can request access to the data once it is delivered to CDC. No interim data will be available except to CDC and either UW or JHU staff funded for the project. While data collection is ongoing CDC staff will require that local IRB approval for research activities is obtained by the University of Washington and Johns Hopkins University to cover all activities which involve interaction with human subjects. The recipients will be responsible for collecting all data for this program. All digital data collected in the computer-assisted self-interview will be stored in an electronic high-security password-protected environment that has undergone a security assessment and meets requirements set forth by the CDC/OCISO. To ensure that respondents# information is protected, a unique study ID will be created for each participant and will be the only identifier included on the data collection instruments. Paper forms, when used, will be filed by the unique ID and date of interview and stored under lock and key; information collected on paper will be entered into the appropriate data system at the clinical study site and the paper forms will be destroyed within 5 years after the study has ended. In addition to the data policy, the recipient is required to implement security procedures for any recipient systems, and information contained therein that cover all aspects of data handling for hard copy and electronic data: # Ensure project data are secured against improper disclosure or unauthorized use of information. # Access information only on a need-to-know basis when necessary in the performance of assigned duties. # Notify their supervisor, the Project Director, and the organizational Security Officer, within one (1) hour or less, if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner. # Report immediately to both the Project Director and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.
Plans for Archival and Long Term Preservation:	Six months before the end of the of the cooperative agreement, the recipients and CDC will determine a data disposition plan. The data disposition plan may include several actions including purging or destroying data, moving data to less expensive or more secure storage like the cloud or offline, copying files to legal hold archives, or encrypting sensitive content to protect against breaches. CDC will receive only deidentified data and specimens. Data will be stored at CDC in secure servers with access limited to CDC staff who request it through the data sharing/analysis proposal process. Specimens will be archived and stored in the CDC Biorepository

Spatiality

Country	State/Province	County/Region
United States	Washington	King
United States	Maryland	Baltimore

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...