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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Rapid HIV Home-Testing among MSM Trial - New - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Innovative testing strategies are needed to reduce levels of undiagnosed HIV infection and increase early access to treatment. Rapid home HIV tests may play an important role in efforts to reduce both HIV morbidity and mortality. Given the unrelenting HIV crisis among MSM and the release into the market of a rapid HIV test for at-home use, it is necessary to evaluate the impact of providing rapid HIV home-test kits on repeat HIV testing, linkage to care, partner testing, serosorting, and HIV sexual risk behaviors among MSM. This information will assist the Division of HIV/AIDS Prevention (DHAP) in developing recommendations, future research and program needs concerning home-testing for MSM.

Specific aims

This study is a randomized trial which aims to evaluate the use and effectiveness of home-test kits as a public health strategy for increasing testing among MSM. A secondary aim of the randomized trial is to evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute HIV home-test kits to their social and sexual networks.

The population for the randomized trial will be men over the age of 18 years who self-report that they have had anal sex with at least one man in the past year. We will recruit approximately 3,200 men who report their HIV status to be negative or who are unaware of their HIV status and 300 men who

self-report that they are HIV-positive. Men will be recruited from the 12 cities: Atlanta, Baltimore, Chicago, Dallas, the District of Columbia, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, and San Juan. We will ensure that at least 20% of participants are black and at least 15% are Hispanic. Recruitment will be conducted through banner advertisements displayed on social networking sites such as Facebook and dating and sex-seeking sites such as Manhunt and Adam4Adam.

This study also has a qualitative component that aims to examine the experiences of participants in the randomized control trial. Participants for the qualitative data collection will be drawn from the randomized control trial. Two data collection techniques will be used: focus group discussions (FGD) (both online and in-person) and individual in-depth interviews (IDIs).

CDC is requesting approval for a 3-year clearance for data collection. All participant consenting and data collection for the RCT will be completed using an online reporting system. Data will be collected using an eligibility screener, an online study registration process, a baseline survey, HIV test results reporting system, and follow-up surveys. Men will be asked to use the study web site or download and access a secure cell phone application prior to enter results of their rapid HIV

home-tests that they receive and conduct at home and to take the follow-up surveys which will collect information on HIV testing results and behaviors and sexual activities. Focus group discussions and in-depth interviews will be used to examine experiences of participants in the RCT.

The duration of the eligibility screener is estimated to be 5 minutes; the RCT consent 10 minutes; the study registration process 5 minutes; the baseline survey 15 minutes; the reporting of home-test results 5 minutes; the follow-up surveys 10 minutes; the focus group and individual interview consents 10 minutes each; the focus group discussion 1 hour and 30 minutes; and the in-depth interviews 1 hour and 15 minutes.

There is no cost to participants other than their time. The total estimated annual burden hours are 7,085.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Hours Per Response
Prospective Participant	Eligibility Screener	24,000	1	3/60
Enrolled participant	Study Registration	14,000	1	5/60
Enrolled participant	Consent for RCT	3,200	1	10/60
Enrolled participant	Baseline Survey for RCT	3,200	1	15/60

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Hours Per Response
Enrolled participant	Baseline Survey for HIV-positive group	300	1	15/60
Enrolled participant	Reporting of Home-test Results during study	1,600	3	5/60
Enrolled participant	Follow-up Surveys for RCT	3,200	4	10/60
Enrolled participant	Follow-up Surveys for HIV positive group	300	2	10/60
Enrolled participants	Reporting of Home-test Results at completion of study	3,200	1	5/60
Enrolled participant	Focus group consent	216	1	10/60
Enrolled participant	Focus group discussion	216	1	1.5
Enrolled participant	Individual in-depth interview guide consent	30	1	10/60
Enrolled participant	Individual in-depth interview guide	30	1	1.5

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