

**Title:** Provision of HIV Self-Test Kit to Emergency Department Patients

**NCT No:** NCT03021005

**Document Type:** Inform Consent Form (High Risk Patients and Testing Decliners, resepctively)

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## ORAL CONSENT SCRIPT

**Protocol Title: Provision of HIV Self-Test Kit to Increase Uptake of HIV Testing among Emergency Department Patients Who Decline Emergency Department-Based HIV Screening.**

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Hi,

You are being asked to take part in a research study. The purpose of this study is to learn if a person would more likely test for HIV on a regular basis at home if HIV a self-testing kit can be easily requested and shipped to home, how we could encourage patients to be tested for HIV, and how we could encourage patients' partners and friends to get tested for HIV. According to your responses to our screening questions, you might have some increased risk for HIV.

If you participate in this study, we will ask you to do and share several things. We expect the study to take approximately 5-10 minutes of your time today.

First, we will ask you to share your contact information (phone number, email address and home address) so we can call you in about 1 month and 3 months from now to ask you if you had an HIV test done since your visit today.

We will also ask you to fill out a short survey. In this survey, we will ask questions about your risks for HIV, HIV tests you have done in the past, your attitudes and opinions about HIV self-testing at home, and your attitudes and opinions about referring your partners or friends for a free HIV self-testing kit through an internet website. You may refuse to answer any question(s) that you do not wish to answer. Your responses to the questions will not have any impact your treatment or care today.

After you complete the survey, you will be randomized (chosen at random like a coin toss) to either receive a free take-home test or to not receive a free take-home HIV test.

If you receive the free take-home HIV test, you will also receive 5 cards to give to your partner(s) and/or friends so they can request their own HIV self-testing kit.

We will also collect information about your emergency room visit today including the reason for your visit and what tests and treatments your doctor ordered. If you agree to be in the study, we would like your permission to review your medical charts for your visit today. We would like your permission to get contact information from your chart if we cannot reach you by the information that you provide for the study.

If you are in the group with HIV self-testing kit and you take the kit home, we would like to know if you use the kit to test yourself at home following the instructions provided. We would like you to report the test results to a secure website called "I Want the Kit" using the information provided in the kit, and complete a short survey on that website.

If you are in the group without HIV self-testing kit, we will give you a pamphlet telling you about places in Baltimore City where you can receive a free HIV test.

We will call or send you a text message to check on you and remind you of this study within one week after enrollment. We would send you a text message a week prior to the 1 month and 3 month follow up as a reminder. Then, we will call you about 1 month and 3 months later to see if you had an HIV test done since we last talked.

If you are in the group without HIV self-testing kit, we will mail you the gift card within a week after completing on the follow-up phone survey. If you are in the group that receives the HIV self-testing kit, we encourage you to test yourself using the HIV self-testing kit at home, report the result on the website, and complete the questionnaire on the "I Want the Kit" (IWTK) website." We will mail you a \$10 gift card within one week after completing the follow-up phone survey. Upon reporting your test results to the website, you would be included in a lottery to have a 1 in 10 chance to win a \$50 gift card. We also encourage you to give out the 5 cards to your friends or partners, so they can request their own HIV self-testing kit. For every person who requests a free kit from the website with the card given by you, you would be included in an additional lottery for a 1 in 10 chance to win a \$10 gift card. Upon winning or not winning a gift card from the lottery, we will contact you to let you know of the outcome by a text message, followed by a phone call.

All research studies have some degree of risk or discomfort. You may experience some discomfort during the surveys. There is some risk that information about you may become known to people outside this study. To protect against this, the study documents will not have any information that could identify you.

One direct benefit is that you will be able to know your HIV status by either testing yourself with the HIV self-testing kit or getting an HIV test by visiting HIV-testing walk-in places in the city. There is no other direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your care at Johns Hopkins.

If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the Johns Hopkins Institutional Review Board (IRB) at 410-955-3008.

We will collect information about you in this study.

People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information.

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who need to make sure the study is being done correctly.

These people will use your information for the purpose of the study.

We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and don't want your information used for the study anymore, you can call The Johns Hopkins Institutional Review Board at 410-955-3008. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but we cannot guarantee this.