ANNEXES TO THE PROTOCOL AND STANDARD OPERATIONAL PROCEDURES

BIOLOGICAL AND BEHAVIORAL SURVEY AMONG MEN WHO HAVE SEX WITH MEN IN UKRAINE (2024)

CONTENT

Annex 1

VERBAL INFORMED CONSENT
to be interviewed (formative assessment stage)

Hello, my name is _____. I ask you to participate in the formative assessment, which is held by _____ as preparation stage for the "Integrated bio-behavioral surveillance among men who have sex with men in Ukraine" (IBBS MSM).

The main objectives of this assessment are:

- the feasibility of conducting the study in your city, potential threats and obstacles to conducting the study;
- the possibility of applying the methods envisaged by the study;
- specification of unique features of the MSM population in your city, their usual social environment, typical personal networks and the possibility of achieving the target sampling size, sexual and other practices of MSM, attitudes/actions of social groups and stakeholders in the city towards MSM;
- selection of criteria for primary respondents (seeds);
- selection of study site (location) to conduct interviewing and testing.

Procedures, privacy and confidentiality. The interview will take approximately 45 minutes. During the interview, you will be asked about your expertise and opinions on the characteristic of MSM and the feasibility of conducting the study in your city. If you agree to participate, we will protect your privacy. No identifying information will be kept in the file containing your responses from this interview. This helps ensure your name will not be used in any reports.

As the study sponsor, USA Center for Disease Control and Prevention (CDC) can monitor and audit procedures within the framework of the survey. The reason for this is to ensure that the survey is conducted in a manner stipulated by the requirements. It will also help to make sure that your rights and health are protected. Your personal health information will be kept confidential.

Potential risks, discomforts and right to refuse. We would not ask you about any personal information. Participating in this interview is voluntary. You can decide not to answer questions or to stop the interview at any time.

Anticipated benefits. Your answers will help us to plan and prepare to the national IBBS MSM. Its results will be used for outreach activities, planning, monitoring and evaluation of the effectiveness of prevention programs, programs of treatment, care and support among MSM.

Identification of investigators. If you have questions or concerns about your rights as a study participant, you can call anonymously

the Regional coordinator by phone _____,

the National coordinator by phone (_____,

or to the Institutional Review Board of SI "Public Health Center MoH of Ukraine" by phone 044-425-56-80.

Subject's rights. If you agree to be in this study, you do not lose any of your legal rights. This consent form means that you have heard or have read the information about this study and that you agree to participate.

Participation and withdrawal. To be in this study is voluntary. You have the right to choose not to be in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. If you choose to take part in the interview, you have the right to stop at any time.

Annex 2

FORMATIVE ASSESSMENT RESULTS FORM
(working meeting)

Town/city: _____

Date: _____

Full name of the person responsible for the working meeting: _____

Role in the survey: _____

1. WORKING GROUP PARTICIPANTS (KEY INFORMANTS)

№	Key informant position	Place of his/her work (name of the organization/company) except for representative of the target group	Recruiter
1			
2			
3			
4			

2. CHARACTERISTICS OF SEEDS (PRIMARY RESPONDENTS)

№	Age	Sexual orientation	Prevention program client status	District of residence	Socio-economic status according to self-declaration
1					
2					
3					
4					
5					
6					

2.1. Comments on specific characteristics of the selected primary respondents (seed)

2.2. Difficulties encountered during recruitment of primary respondents

3. CHARACTERISTICS OF THE SURVEY SITE

Type of site	Main	Alternative 1	Alternative 2
The building in which the site is located			
City district			
Convenient location of the site			
The floor on which the site is located			
Technical conditions of Internet connection			
Number of rooms			
Remoteness of rooms from each other			
Rental price for 1 month			
Other			

3.1. Comments on survey site

Type of the site	Advantages of the site	Weakness of the site	Comments on the site
Main			
Alternative			
Alternative			

4. SITE WORKING HOURS

Weekday	Opening hours	Closing hours	Comments and suggestions on the proposed working hours
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

5. LIST OF ADDRESS FOR REFERRAL (includind for minors that can be victims of violence, child trafficking or sexual exploitation)

Name of the organization	Address	Telephone number	Services Provided

6. AMOUNT OF COMPENSATION FOR PARTICIPANTS

Key informant	Participation in the survey (interview and testing)	Arguments and comments	Recruitment of other participants (per 1 recruited participant)	Arguments and comments

7. SAMPLE REALIZATION

7.1. Is it realistic for your city to reach the planned sample within the survey timeframe?

7.2. If not, please, specify the reasons and realistic timing to achieve the planned sample size.

8. Is it realistic for your city to collect information for population estimation methods based on the willingness to share the phone numbers of friends?

9. COMPOSITION OF THE SURVEY TEAM

№	Role within the survey	Full name	Telephone number	E-mail address	Confidential consent is signed
1	Regional coordinator				
2	Biological component coordinator				
3	Interviewers (interview)				
4	Medical staff (testing)				
5	Coupon manager				
6	Social worker				

Annex 3

LOG OF COMPENSATION TO THE KEY INFORMANTS
(formative assessment stage)

Town/city: _____

Regional coordinator: _____

№	Date	Key informant 's place of work (name of organization/company) except for representative of the target group	Amount, in UAH	Signature of key informant	Full name of the interviewer	Signature of the interviewer

Annex 4

VERBAL CONSENT
to questionnaire piloting

Hello, my name is _____. I ask you to participate in the formative assessment, which is held by _____ as preparation stage for the "Integrated bio-behavioral surveillance in key populations in Ukraine" (IBBS MSM).

Now we have preparation stage for IBBS and ask you to participate in the survey with purpose to pilot our questionnaire. We are going to ask you questions with the purpose to receive not only your responses to those questions but also your feedback and comments about questions' wording, their unambiguous, and the response options.

Procedures, privacy and confidentiality. The interviews will take approximately 45 minutes. During the interview, you will be asked questions about your sexual behavior, drug usage experience, participation in the prevention and treatment programs, HIV-testing experience, etc.. If you agree to participate, we will protect your privacy. No identifying information will be kept containing your responses from this interview. This helps ensure your name will not be used in any reports. All interviews are anonymous. Paper records are kept locked and will be used only with the purpose to improve the questionnaire before its use in the IBBS. You will not be considered as a participant of the main survey (but you can still later participate in it if eligible and recruited).

As the study sponsor, USA Center for Disease Control and Prevention (CDC) can monitor and audit procedures within the framework of the survey. The reason for this is to ensure that the survey is conducted in a manner stipulated by the requirements. It will also help to make sure that your rights and health are protected. Your personal health information will be kept confidential.

Potential risks, discomforts and right to refuse. We would not ask you about any personal information. Participating in this interview is voluntary. You can decide not to answer questions or to stop the interview at any time.

Anticipated benefits. You will not receive any benefit from being in this study. Your answers will help us to prepare to the IBBS and to develop questionnaire, which will be correctly understood by people like you.

Alternatives. Your alternative is not to participate in the study. If you choose not to participate, you will be able to receive any HIV services that are now available to you. No services, nor access to services, will be taken away from the individual whether they choose to participate or not.

Subject costs and payments. You will be compensated 305 UAH (10$) in cash for your time and travel cost required for completing the interview. It will not cost you any money to be in the study.

Identification of investigators. If you have questions or concerns about your rights as a study participant, you can call anonymously

the Regional coordinator by phone _____, the National coordinator by phone _____, or to the Institutional Review Board of SI "Public Health Center MoH of Ukraine" by phone 044-425-56-80 (on working days from 9.00 p.m. to 5.00 a.m.).

Subject's rights. If you agree to be in this study, you do not lose any of your legal rights. This consent form means that you have heard or have read the information about this study and that you agree to participate.

Participation and withdrawal. To be in this study is voluntary. You have the right to choose not to be in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. If you choose to take part in the interview, you have the right to stop at any time.

Annex 5

LOG OF COMPENSATION TO THE RESPONDENTS FOR QUESTIONNAIRE PILOTING

Town/city: _____

Regional coordinator: _____

№	Date	Respondent ID	Amount, in UAH	Signature of the respondent *(or any mark (for example, "+"))*	Full name of the interviewer	Signature of the interviewer

Annex 6

SCREENING QUESTIONNAIRE FOR PRIMARY RESPONDENTS

Town/city: _____
Full name of Regional coordinator: _____
Signature of Regional coordinator: _____
Full name of Interviewer: _____
Signature of interviewer: _____

Good afternoon! My name is _____, and I represent _____ contracted by the State Institution "Public Health Center of the Ministry of Health of Ukraine". We are conducting a survey on health issues. The purpose of this survey is to collect data on dissemination of various health related behavioral practices, as well as to determine prevalence of HIV infection, anti-hepatitis C antibodies and syphilis. The survey findings will help governmental and non-governmental organizations to improve services provision to MSM and make these services more useful. Your participation as well as your opinion and propositions are very important and valuable to us. Thank you in advance for your time!

1. Did you have at least one oral or anal sexual contact with a male within the last 6 month?

1	Yes	→	CONTINUE
2	No	→	COMPLETE

2. Have you lived/studied/worked in this city for at least 3 months? *(meaning permanent residence, not a residence permit)*

1	Yes	→	CONTINUE
2	No	→	COMPLETE

3. How many men who have sex with men and live in your city do you know (do you know their names and do they know yours)?

	persons		
Interviewer, encode:			
1	7 and more	→	CONTINUE
2	Less than 6	→	COMPLETE

4. Are you ready to share the information about the survey among your acquaintances who have sex with men?

1	Yes	→	CONTINUE
2	No	→	COMPLETE

5. In what city district do you live? *(primary respondents have to live in different districts of the city)*

	district

6. How old are you? (specify the number of full years) *(primary respondents must be of different age categories)*

1	Under 16 years old	→	COMPLETE
2	From 16 to 19 years	→	CHECK QUOTA
3	From 20 to 25 years	→	CHECK QUOTA
4	26 years and older	→	CHECK QUOTA

7. Are you a client of an organization that works with MSM, organization operating in the field of HIV prevention? *(primary respondents must be both clients and non-clients)*

1	Yes	→	CHECK QUOTA
2	No	→	CHECK QUOTA

8. Which of the following describes your sexual orientation better? *(primary respondents must have various financial situation)*

1	Heterosexual	→	COMPLETE
2	Bisexual	→	CHECK QUOTA
3	Homosexual	→	CHECK QUOTA

9. How would you characterize your financial situation? *(primary respondents must have various financial situation)*

1	I do not have enough money even for food	→	CHECK QUOTA
2	I have enough money for food, but I almost cannot afford buying clothes		
3	I have enough money for food, clothes and I can save a bit, but I cannot afford to buy expensive things (such as a fridge or TV)	→	CHECK QUOTA
4	I can afford some expensive things (such as a fridge or TV)	→	CHECK QUOTA
5	I can afford to buy everything I want		

Annex 7

INTRODUCTION FOR THE POTENTIAL PARTICIPANTS OF THE SURVEY

Good afternoon! My name is _____. I represent the State Insitution "Public Health Center of the Ministry of Health of Ukraine".

We conduct a survey on health issues. The purpose of this survey is to collect data on dissemination of various behavioral practices, as well as to determine the prevalence of HIV infection, hepatitis C and syphilis. The survey findings will help governmental and non-governmental organizations to improve services provision for MSM and make these services more useful. Your participation as well as your opinion and propositions are very important and valuable to us.

You can take part in the survey if you have a participant's coupon received from an acquaintance, a person you know or a friend.

Annex 8

CHECKLIST FOR SCREENING

Filled by the coupon manager

Survey ID _____ Date _____

Ask the respondent

Age _____ years (if age under 16 - ineligible)

Do you live or spent the most of the time in this city?

- yes
- no -> **INELIGIBLE**

Do you have sexual intercourse with the male partner in the last 6 months?

- yes
- no -> **INELIGIBLE**

Where do you usually find your male partners? _____

Filled by coupon manager

Is recruit's coupon valid?

- yes
- no -> **INELIGIBLE**

Where did you get the coupon? _____

Who gave you this coupon? _____

How many times did you see this person in the last 30 days? _____

Was your coupon exchanged for something?

- yes-> **INELIGIBLE**
- no

Have you participated in the similar surveys in the last 6 months?

- yes -> **INELIGIBLE**
- no

Filled by coupon manager

State of alcohol or drugs intoxication, which does not allow recruit to understand and answer questions of the questionnaire

- yes -> **INELIGIBLE**
- no

Filled by coupon manager

Is this man fully eligible to be enrolled into the study?

- yes
- no -> **why? (write the reason)** _____

Signed by coupon manager _____

Annex 9

SURVEY PARTICIPANT'S COUPON

Dear participant, we are waiting for you with this coupon to take part in a health survey.
If you meet the survey eligibility criteria, you will be given the opportunity to participate in the survey and receive compensation.

This coupon may be not accepted in the following cases:
1. The survey involved a sufficient number of participants.
2. This coupon has been terminated (damaged), forged or is impossible to read.
3. The owner of this coupon has already taken part in an interview.

RECRUITER NUMBER (*write in*):

For the respondent **Keep this coupon**	**For healthcare worker**
Stick a code	*Stick a code*

YOUR PARTICIPATION IN THE INTERVIEW IS VOLUNTARY AND ANONYMOUS!

Venue address: _____

We are waiting for you from ___: ___ to ___: ___ on such week days:_____

Contact phone number: _____

(you can call this number if you want to know more about the survey)

COUPON IS VALID FROM:

COUPON IS VALID UNTIL: _____**(dd/mm/2021)**

DATE OF COUPON ISSUE: _____**(dd/mm/2021)**

Annex 10

PARTICIPANT'S CARD

Participant's card

Participant's ID-code: _____

Coupon manager signature: _____

Interviewer signature: _____

Healthcare worker signature: _____

Coupon manager signature: _____

Date of participation: _____ / _____ / _2024
(dd/mm/yy)

Annex 11

PARTICIPANT'S INFORMED CONSENT
(in Ukrainian language)

ID учасника: _____

Ми просимо Вас взяти участь у дослідженні. Дослідження проводиться _____. Ви були залучені до дослідження Вашим другом, який також взяв участь у цьому дослідженні та вирішив передати Вам купон. Усі компоненти дослідження заберуть 1-2 години Вашого часу. Участь у цьому дослідженні є добровільною.

Мета дослідження полягає у вивченні поведінкових практик та орієнтацій ЧСЧ в контексті ВІЛ, вивчення факторів, що можуть бути пов'язані з ВІЛ. Результати дослідження будуть використані для оцінки програм профілактики та лікування серед ЧСЧ.

Як відбуватиметься це дослідження. Ви – один із близько 4,000 учасників цього дослідження. Воно проводиться у 10 містах, Ваше місто – лише одне із них. Ми попросимо Вас взяти участь у нашому дослідженні, яке включає наступні компоненти: особисте інтерв'ю віч-на-віч, дотестове консультування, тестування на ВІЛ (швидкий тест), антитіла до гепатиту С та сифілісу, післятестове консультування. Протягом інтерв'ю ми поставимо запитання щодо Вашої сексуальної поведінки, досвіду вживання наркотиків, участі у програмах профілактики та лікування, досвіду тестування на ВІЛ, і т. п. Щоби зробити швидкий тест, ми зробимо забір крові за допомогою пробірки-мікротайнера. Якщо результат тесту на ВІЛ виявиться позитивним, ми зробимо ще два тести для підтвердження результату. Якщо всі три тести виявляться позитивними, ми проведемо лабораторний аналіз для підтвердження ранньої інфекції і визначення вірусного навантаження в крові. Залишки зразків можуть бути використані для верифікації алгоритму тестування на ВІЛ, або для потреб молекулярного епідеміологічного нагляду. У разі ВІЛ-позитивного результату медичний працівник направить Вас для підтвердження діагнозу, а також лікування та соціального супровду, якщо в цьому буде потреба і якщо Ви будете до цього готові. В разі, якщо в ході дослідження за результатами тестування у Вас будуть виявлені антитіла до вірусного гепатиту С або сифілісу, Вам буде виданий купон, який дозволить протягом двох тижнів безкоштовно пройти тестування в приватній лабораторії для з'ясування, чи є ця інфекція активною. Вам буде надана інформація, яким чином можна встановити діагноз та розпочати лікування (у випадку активного гепатиту С - безкоштовного, активного сифілісу - платного).

Зразки крові, що залишаться, можуть бути використані для перевірки коректності застосування алгоритмів швидкого тестування. Вони також можуть бути використані для інших досліджень з метою оцінки епідемії ВІЛ-інфекції (включаючи молекулярний нагляд). Зібрані зразки крові будуть знищені протягом 5 років з моменту завершення дослідження.

Під час реалізації дослідження не збираються персональні дані про Вас, не здійснюється аудіо- чи відеозапис Вашого інтерв'ю.

Вам може бути відмовлено у проходженні дослідження якщо Ви не відповідаєте вимогам до учасників дослідження, перебуваєте у стані алкогольного чи наркотичного сп'яніння, якщо Ви відмовитесь приймати участь в біологічному або поведінковому компоненті дослідження або якщо буде виявлено, що Ви надаєте про себе недостовірну інформацію.

Перед початком інтерв'ю у Вас буде можливість задати уточнюючі запитання дослідницькій команді та отримати на них відповіді.

Ризики та незручності. У цьому дослідженні ми не передбачаємо для Вас жодних ризиків. Під час інтерв'ю Ви можете пропустити певні запитання, на які Ви не хочете відповідати. Ви можете відмовитись від проходження тестування. В останньому випадку Вам буде відмовлено у проходженні дослідження, і Ви не отримаєте компенсацію.

Потенційні переваги. Участь у дослідженні не дасть Вам жодних переваг. Однак, Ваш досвід у майбутньому може допомогти іншим людям, якщо дослідження покаже, що програма для клієнтів може бути покращена.

Альтернативним варіантом для Вас є відмова брати участь у дослідженні. Якщо Ви вирішите не брати участь у дослідженні, Ви все рівно отримуватимете всі послуги, пов'язані з ВІЛ, якими Ви користуєтесь зараз.

Вартість для суб'єкта та оплата. Ви отримаєте компенсацію готівкою у розмірі 365 грн. якщо пройдете всі етапи дослідження. Ця сума передбачає компенсацію за Ваш час та за транспортні витрати, пов'язані із участю в дослідженні. Якщо Ви погодитесь стати рекрутером, Ви також зможете отримати додаткову винагороду за рекрутинг до участі у дослідженні своїх друзів у розмірі 215 грн. за кожного друга. Купон-менеджер дасть Вам інструкції з рекрутингу після завершення Вашої участі в дослідженні. Участь у дослідженні для Вас буде абсолютно безкоштовною.

Конфіденційність. Усі інтерв'ю є анонімними. Вони міститимуть лише Ваш номер учасника (не Ваше ім'я). В комп'ютер будуть внесені відповіді лише в текстовому форматі. Паперові записи зберігатимуться під замком. Дані не міститимуть Вашого імені. Доступ до даних дослідження матиме виключно персонал дослідження. Інформація, отримана під час Вашого інтерв'ю, буде використана лише для цілей дослідження, однак жодні звіти чи публікації про дослідження не міститимуть Вашого імені. В якості донора Центри з контролю та профілактики захворювань США (CDC), можуть здійснювати моніторинг або аудит активностей в рамках дослідження для впевненості в тому, що дослідження відбувається згідно плану, а також, що Вашим правам та здоров'ю нічого не загрожує. Щодо Ваших персональних медичних даних буде збережена конфіденційність.

Права суб'єкта. Якщо Ви погоджуєтесь на участь у цьому дослідженні, Ви зберігаєте всі свої юридичні права. Підписання цієї форми означає, що Ви почули чи прочитали інформацію про дослідження та погоджуєтесь на участь у ньому. Усі дослідження, у яких беруть участь люди, підлягають експертизі комітету, який займається захистом Ваших прав. Якщо у Вас є запитання чи побоювання щодо дотримання своїх прав як учасника дослідження, Ви можете анонімно зателефонувати до регіонального координатора (ім'я координатора) за телефоном _____, до Національного координатора за телефоном _____ або до Комісії з питань етики Центру громадського здоров'я Міністерства охорони здоров'я України за телефоном 044-425-56-80 (в робочі дні з 09.00 до 17.00).

Право на відмову чи припинення участі. Участь у цьому дослідженні добровільна. У Вас є право відмовитись від участі. Якщо Ви вирішили взяти участь у дослідженні, та змінили свою думку, Ви можете припинити свою участь у дослідженні. Якщо Ви вирішили взяти участь у інтерв'ю, Ви можете зупинитись у будь-який момент.

Підписання цієї форми означає, що Ви прочитали (або Вам прочитали) цю форму, ми відповіли на всі Ваші запитання, та що Ви даєте добровільну згоду на участь у цьому дослідженні. Ви отримаєте підписану копію цієї інформованої згоди.

Підпис учасника: _____ Дата: _____ Час: _____

ПІБ співробітника, який отримав згоду: _____

Підпис співробітника: _____ Дата: _____ Час: _____

Annex 12

PARTICIPANT'S INFORMED CONSENT
(in Russian language)

ID участника: _____

Мы просим Вас принять участие в исследовании. Исследование проводится _____. Вы были привлечены к исследованию Вашим другом, который также принял участие в этом исследовании и решил передать Вам купон. Все компоненты исследования заберут 1-2 часа Вашего времени. Участие в этом исследовании является добровольным.

Цель исследования заключается в изучении поведенческих практик и ориентаций МСМ в контексте ВИЧ, изучения факторов, которые могут быть связаны с ВИЧ-инфекцией. Результаты исследования будут использованы для оценки программ профилактики и лечения среди МСМ.

Как будет происходить это исследование. Вы – один из около 4000 участников этого исследования. Оно проводится в 10 городах, Ваш город – один из них. Мы попросим Вас принять участие в нашем исследовании, которое включает следующие компоненты: личное интервью по методу лицом к лицу, дотестовое консультирование, тестирование на ВИЧ, антитела к гепатиту С и сифилису, послетестовое консультирование. Во время интервью ми зададим Вам ряд вопросов о сексуальном поведении, опыту употребления наркотиков, участии в программах профилактики и лечения, опыте тестирования на ВИЧ. Чтобы провести быстрый тест, мы сделаем забор крови с помощью пробирки-микротайнера. Если результат теста на ВИЧ окажется положительным, мы сделаем еще два теста для подтверждения результата. Если все три теста окажутся положительными, мы проведем лабораторный анализ для подтверждения ранней инфекции, а также определения уровня вирусной нагрузки в крови. В случае ВИЧ-положительного результата медицинский работник направит Вас на подтверждение диагнза, а также на лечение и социальное сопровождение, если в этом будет необходимость и если Вы будете к этому готовы. В случае, если в ходе исследования по результатам тестирования у Вас будут обнаружены антитела к вирусному гепатитусу С или сифилису, Вам будет выдан купон, который позволит в течение двух недель бесплатно пройти тестирование в частной лаборатории для выяснения, является ли эта инфекция активной. Вам будет предоставлена информация, каким образом можно установить диагноз и начать лечение (в случае активного гепатита С – бесплатного, активного сифилиса – платного).

Оставшиеся образцы крови могут быть использованы для проверки корректности применения алгоритмов быстрого тестирования. Они также могут быть использованы для других исследований с целью оценки эпидемии ВИЧ-инфекции (включая молекулярное наблюдение). Собранные образцы крови будут уничтожены в течение 5 лет с момента завершения исследования.

В ходе исследования не собираются персональные данные про Вас, не осуществляется аудио- или видеозапись Вашего интервью.

Вам может быть отказано в прохождении исследования если Вы не соответствуете требованиям к участникам исследования, находитесь в состоянии алкогольного или наркотического опьянения, если Вы откажетесь участвовать в биологическом или поведенческом компоненте исследования или если будет обнаружено, что Вы предоставляете о себе недостоверную информацию.

Перед началом интервью у Вас будет возможность задать уточняющие вопросы исследовательской команде и получить на них ответы.

Риски и неудобства. В этом исследовании мы не предвидим для Вас каких-либо рисков. Тем не менее во время интервью Вы можете в любое время сделать перерыв или отказаться отвечать на некоторые вопросы. Вы можете отказаться от прохождения тестирования. В последнем случае Вам будет отказано в прохождении исследования, и Вы не получите компенсацию.

Потенциальные преимущества. Участие в исследовании не даст Вам никаких преимуществ. Однако, Ваш опыт в будущем может помочь другим людям, если исследование покажет, что программа для клиентов может быть улучшена.

Альтернативным вариантом для Вас является отказ участвовать в исследовании. Если Вы решите не участвовать в исследовании, Вы все равно будете получать все услуги, связанные с ВИЧ, которыми Вы пользуетесь сейчас.

Стоимость для субъекта и оплата. Вы получите компенсацию наличными в размере 365 грн. если пройдете все этапы исследования. Эта сумма предусматривает компенсацию за Ваше время и за транспортные расходы, связанные с участием в исследовании. Если Вы согласитесь стать рекрутером, Вы также сможете получить дополнительное вознаграждение за рекрутинг к участию в исследовании своих друзей в размере 215 грн. за каждого друга. Купон-менеджер сможет предоставить Вам информацию об условиях и инструкцию по рекрутингу после завершения интервью. Участие в исследовании для Вас будет абсолютно бесплатным.

Конфиденциальность. Все интервью являются анонимными. Они будут содержать только Ваш номер участника (не Ваше имя). В компьютер будут внесены ответы только в текстовом формате. Бумажные записи будут храниться под замком. Данные не будут содержать Вашего имени. Доступ к данным исследования будет исключительно у персонала исследования. Информация, полученная во время Вашего интервью, будет использована только для целей исследования, однако никакие отчеты или публикации про исследование не содержат Вашего имени. В качестве донора Центры по контролю и профилактике заболеваний США (CDC), могут осуществлять мониторинг или аудит активностей в рамках исследования для уверенности в том, что исследование происходит согласно плану, а также, что Вашим правам и здоровью ничего не угрожает. Относительно Ваших персональных медицинских данных будет сохранена конфиденциальность.

Права субъекта. Если Вы согласны на участие в этом исследовании, Вы сохраняете все свои юридические права. Подписание этой формы означает, что Вы услышали или прочитали информацию об исследовании и согласны принять участие в нем. Все исследования, в которых принимают участие люди, подлежат экспертизе комитета, который занимается защитой Ваших прав. Если у Вас есть вопросы или опасения относительно соблюдения своих прав как участника исследования, Вы можете анонимно позвонить региональному координатору (имя координатора) по телефону _____, или Национальному координатору по телефону _____ или в Комиссию по вопросам этики Центра общественного здоровья Министерства охраны здоровья Украини по телефону 044-425-56-80 (в рабочие дни с 09.00 до 17.00).

Право на отказ или прекращение участия. Участие в этом исследовании добровольное. У Вас есть право отказаться от участия. Если Вы решили принять участие в исследовании, и изменили свое мнение, Вы можете прекратить свое участие в исследовании. Если Вы решили принять участие в интервью, Вы можете остановиться в любой момент.

Подписание этой формы означает, что Вы прочитали (или Вам прочитали) эту форму, мы ответили на все Ваши вопросы, и что Вы даете добровольное согласие на участие в этом исследовании. Вы получите подписанную копию этого информированного согласия.

Подпись участника: _____ Дата: _____ Время: _____

ФИО сотрудника, который получил согласие: _____

Подпись сотрудника: _____ Дата: _____ Время: _____

PARTICIPANT'S INFORMED CONSENT
(in English)

Participant ID: _____

We ask you to participate in the survey. Survey is held by _____. You were recruited by your friend who also had participated in this study and made a decision to give you a recruitment coupon. All components of the study will take about 1-2 hours of your time. Taking part in this study is voluntary.

The purpose is to study the behavior, knowledge and attitude of MSM in the context of HIV/AIDS, to survey factors that associated with HIV. The result of the survey will be used to evaluate the effectiveness of prevention and treatment programs among MSM.

What happens in the survey. You will be one of about 4,000 individuals who are in this survey. The survey is being implemented in 10 cities, your city is one of them. The survey has these components: a face-to-face interview, pre-test-counseling, and tests for HIV, antibodies to HCV and syphilis, post-test counseling. During the interview, we will ask you questions about your sexual behavior, drug usage experience, participation in the prevention and treatment programs, HIV-testing experience, etc. The testing will be done using a microtainer tube to draw a small amount of blood from finger prick. If result of the HIV rapid test will be positive, we will do two additional HIV tests to confirm the result. In case if all three tests are positive, we will perform laboratory analysis to verify the recent or long-term HIV-infection result and to measure the VL level in the blood. In case of HIV-positive result the medical worker will refer you for confirmatory diagnosis and care and treatment if needed and you are ready. If the test results show that you have antibodies to hepatitis C virus or syphilis, you will be given a coupon that will allow you to undergo free testing in a private laboratory within two weeks to find out if the infection is active. You will be provided with information on how to make a diagnosis and start treatment (in case of active hepatitis C - free of charge, active syphilis - paid).

The remnant specimens can be used to verify the correctness of rapid testing. They may be also used for other studies to assess HIV epidemics (including molecular surveillance). The collected blood samples will be destroyed within 5 years from the date of completion of the study.

During the survey, no personal data about you is collected, no audio or video recording of your interview is conducted.

You may be denied the possibility to take part in the survey if you do not meet the requirements for survey participants, are under the influence of alcohol or drugs, refuse to participate in the biological or behavioral component of the survey, or are found to be providing inaccurate information about yourself.

Before starting the interview, you will have the opportunity to ask clarifying questions to the survey team and have them answered.

Risks and discomforts. We do not anticipate any risks to people in this survey. However you can skip or not answer some question that you do not want to answer. You can refuse to be tested. If you do, you will be denied the possibility to take part in the survey and you will not receive compensation.

Potential benefits. You will not receive any benefit from being in this survey. However, the information you provide will be helpful to better plan HIV programs in Ukraine.

Alternatives. Your alternative is not to participate in the survey. If you choose not to

participate, you will be able to receive any HIV services that are now available to you. No services, nor access to services, will be taken away from you whether you choose to participate or not.

Subject Costs and Payments. You will be compensated 365 UAH ($12 equivalent) in cash for your time and travel cost required for completing the survey. You will receive additional compensation for recruitment of your peers, 215 UAH ($7 equivalent) for each eligible peer. The instructions about recruitment you will receive after your participation in the survey from the coupon manager. It will not cost you any money to be in the survey.

Confidentiality. All interviews are anonymous. They will include only your participant ID (not your name). Only answers in text format will be entered into the computer. Paper records are kept locked up and electronic datasets are in password protected computers. The data will not have your name. Only survey staff will have access to the data. Information from your interview will be used only for research purpose. We will not have your name in any reports or publications. As the survey sponsor, CDC may monitor or audit survey activities. The reason for this would be to make sure that the survey is being done the way it is supposed to be done. It would also make sure that your rights and health are protected. Your personal medical information will be kept confidential.

Subject's Rights. If you agree to be in this survey, you do not lose any of your legal rights. Signing the consent form means that you have heard or have read the information about this survey and that you agree to participate. All research with people is reviewed by a committee that works to protect your rights. If you have questions or concerns about your rights as a survey participant, you can call anonymously your Regional Coordinator at _____ (Coordinator name),National Coordinator at _____ or the Institutional Review Board of SI “Public Health Center MoH of Ukraine” at 044-425-56-80 (on working days from 9.00 a.m. to 5.00 p.m.).

Right to Refuse or Withdraw. To be in this survey is voluntary. You have the right to choose not to be in this survey. If you decide to be in the survey and then change your mind, you can withdraw from the research. If you choose to take part in the interview, you have the right to stop at any time.

Signing this consent form means that you have read this form (or someone has read it to you), we answered all your questions and you voluntarily agree to be in this survey. You will receive a copy of this signed consent form.

Participant (Signature): _____ **Date:** _____ **Time:** _____

Person Obtaining Consent (Signature and Name): _____

Date: _____ **Time:** _____

Annex 13

REGISTRATION FORM FOR REFUSAL TO PARTICIPATE IN THE SURVEY
(Non-response form)

Town/city: _____

Regional coordinator: _____

№	Date	ID-code	Initiator of refusal		Full name of the survey team member, who registered the refusal	Signature	Reason for refusal
			Participant	Team member			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			
			1	2			

Annex 14

QUESTIONNAIRE OF REFUSAL TO PARTICIPATE IN THE SURVEY FOR RECRUITERS

Town/city: _____

Participant ID-code: _____

1. Please, tell us, to how many representatives of your social network have you offered coupons to participate in the survey? Please, specify in chronological order the information about them.

№	Age	Agreed to participate or not		If not, specify the reason to refuse participation in the survey?
		Yes	No	
1		1	2	
2		1	2	
3		1	2	
4		1	2	
5		1	2	
6		1	2	

2. In your opinion, what could motivate your friends who refused to take part in the survey?

3. Specify coupon information:

3.1.	The number of coupons you received to distribute among your friends	
3.2.	The number of coupons that you managed to distribute among your friends	
3.3.	How much time it took to distribute coupons	

4. What difficulties did you encounter while distributing coupons to participate in the survey among your friends? Please describe it in details.

Annex 15

TEST RESULTS FORM

Town/city: _____

Place to glue a participant coupon

Survey ID	
Testing date	
Testing time	

CAPILLARY BLOOD SAMPLING	Y – conducted, N – not conducted	
HIV test result	Y – positive, N – negative, I – invalid	
HIV CONFIRMATORY TEST	Y – conducted, N – not conducted	
If Y - the result of the first confirmatory test	Y – positive, N – negative, I – invalid	
If Y - the result of the second confirmatory test	Y – positive, N – negative, I – invalid	
THE RESULT OF HIV TESTNG DBS SAMPLING	Y – positive, N – negative, U - uncertain Y – conducted, N – not conducted	
ANTI-HEPATITIS C test result	Y – positive, N - negative, I – invalid	
If Y – Does the participant registered with HCF?	Y – yes, N –no, DN – don't know	
ANTI-SYPHILIS test result	Y – positive, N - negative, I – invalid	
If Y – Does the participant registered with HCF?	Y – yes, N –no, DN – don't know	

POST-TEST CONSULTATION	**NOTIFICATION ABOUT TEST RESULTS**	

M1. Does respondent first know about his HIV status?	Y – yes
	N – no 99 – N/A

M2. Registration at the AIDS Center before the survey	Y – yes
	N – no
	DN – don't know
M3. ART receiving at the time of the survey?	1 - yes
	2 - no, but doctor has already prescribed
	3 - was received ART, but stopped
	4 – no
	5 - respondent says no, but I know him and know about his receiving ART
	6 - don't know 7 - respondent take PReP

1 – Referral respondent for taking medical help because of getting positive HIV test results	1 – Yes 2 – No (refuse from referral)
Referring participants with positive HCV/syphilis antibody test results for testing for the corresponding active infection	
2 – ANTI-HEPATITIS C	1 – Yes 2 – No (refuse from referral)
3 - ANTI-SYPHILIS	1 – Yes 2 – No (refuse from referral)

Full name and signature of healthcare worker: _____

Annex 16

REFERRAL FORM FOR THE SURVEY PARTICIPANT (if any test positive)

Referral to confirm positive result of the rapid test of the survey participant

Participant ID: _____

Name of healthcare facility: _____

Address of the healthcare facility: city_____ street_____ building No.____

Physician's office №_____ Working days and hours: _____- _____from _____untill _____

Physician's full name: _____ Contact phone number: _____

Full name of the organization involved in the survey:

_____

The name and signature of the healthcare worker who issued the referral:

_____

Date of issuing referral ____ / ____ / _____

Date of visit to a healthcare facility ____ / ____ / _____

Full name and signature of the admitting physician: _____

Annex 17

CERTIFICATE OF HIV TEST RESULTS

CERTIFICATE of HIV test results

Issued to (Participant ID): _____

during testing (screening, confirmation, identification) from _____ / _____ / _____ :

1. Antibodies to HIV ½ have not been detected. The person does not need further examination.
2. Antibodies to HIV ½ have not been detected. The person should be referred to the appropriate health care institution for medical examination.
3. Antibodies to HIV ½ have not been detected. The person's HIV-positive status is confirmed (identification stage).
4. Only HIV-1 p24 antigen was detected. The person should be referred to the appropriate health care institution for examination to determine the level of viral load of HIV-1.
5. An uncertain result was obtained. A person is advised to undergo a follow-up examination after 14 days.
6. An uncertain result was obtained. A person is advised to undergo a follow-up examination after 1 month.

Full name and a signature of the healthcare worker who conducted the test and issued medical certificate:

_____

Annex 18

CERTIFICATE OF TEST RESULTS FOR HEPATITIS C, SYPHILIS

CERTIFICATE
of test results for hepatitis C, syphilis

Issued to (Participant ID): _____

to certify that rapid test of his/her blood samples as part of a survey:

_____

the antibodies to hepatitis C_____ syphilis_____ have been detected / not detected.

Date of testing: _____ / _____ / _____ Date of medical certificate issue: _____ / _____ / _____

Full name and signature of the healthcare worker who conducted the test and issued medical certificate:

_____

Annex 19

SOCIAL SUPPORT REFERRAL FORM FOR THE SURVEY PARTICIPANT

SOCIAL SUPPORT REFERRAL FORM
for the survey participant

Participant ID: _____

The name of non-governmental organization: _____

Address of non-governmental organization: city_____ street_____ building No. ___

Office №_____ Working days and hours: _____- _____from _____untill _____

Full name of social worker: _____ Contact phone number: _____

Full name of the organization involved in the survey:

_____

The name and signature of the healthcare worker who issued the referral:

_____

Date of referral issuing: _____ / _____ / _____

Date of visit to non-governmental organization: _____ / _____ / _____

Full name and a signature of admitting social worker:_____

Annex 20

REGISTRATION LOG FOR REFERRALS to health care institution providing medical care for HIV infection

Town/city: _____

Regional coordinator: _____

№	ID-code	Date of issue	Contact telephone of the respondent (if agreed to provide)	Has the respondent visited health care institution providing medical care for HIV infection		If the respondent visited the health care institution providing medical care for HIV infection			Signature of healthcare worker
				Yes	No	Date of visit	Date of registration	Date of ART	
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				
				1	2				

Annex 21

REGISTRATION LOG FOR REFERRALS TO HEALTHCARE FACILITIES (HCF)

Town/city: _____

Regional coordinator: _____

№	ID-code	Date of issue	Contact telephone of the respondent (if agreed to provide)	The name of the HCF, where the person has been referred to	Name of the STD referred for confirmation	Has the respondent used voucher and been tested for active infection in private laboratory?		Date of testing for active infection	Has the respondent visited the HFC?		If the respondent visited the HFC			Signature of healthcare worker / social worker
						Yes	No		Yes	No	Date of visit	Date of registration	Date of treatment	
1									1	2				
2									1	2				
3									1	2				
4									1	2				
5									1	2				
6									1	2				
7									1	2				
8									1	2				
9									1	2				
10									1	2				
11									1	2				
12									1	2				
13									1	2				
14									1	2				

Annex 22

FORM OF REJECTED DBS SAMPLES

Town/city: _____

№	ID-code (rejected DBS sample number)	Reason for DBS rejection	Full name of the person conducting DBS	Date of DBS samples rejection	Has the respondent undergone DBS re-testing		Date of DBS re-testing	The way the DBS re-testing has been conducted?	Full name of the person who conducted the DBS re-testing
					No	Yes			
1					1	2			
2					1	2			
3					1	2			
4					1	2			
5					1	2			
6					1	2			
7					1	2			
8					1	2			
9					1	2			
10					1	2			

Annex 23

DBS REGISTRATION FORM

Town/city: _____

№	The DBS sample number (ID-code)	Full name of the person conducting DBS collection	Date of DBS collection	Date of passing of DBS sample to the medical coordinator (not filled in for the rejected DBS samples)	Sent date of DBS samples by a medical coordinator (not filled in for rejected DBS samples)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Annex 24

FORM OF ROUTINE FORWARDING OF THE DBS SAMPLES TO THE REFERENCE LABORATORY

FORM OF ROUTINE FORWARDING OF THE DBS SAMPLES,
transported to Reference laboratory

Name of the city the DBS samples are transported from: _____

Number of DBS samples transported to a reference laboratory: _____

Transportation date of DBS samples to a reference laboratory: _____ / _____ / _____

Full name and signature of responsible person/regional coordinator:

_____

Date of sample receipt by a reference laboratory: _____ / _____ / _____

Full name and signature of a responsible person in reference laboratory:

_____

Annex 25

COMPENSATION LOG

Town/city: _____

Regional coordinator: _____

Full name of the coupon manager: _____

№	Respondent ID-code	Date of participation	Compensation for participation amount, in UAH	Participant signature	Issued coupons	Compensation for participation amount, in UAH	Date of compesation receipt	Participant signature
1								
2								
3								
4								
5								

Annex 26

INSTRUCTIONS FOR A RECRUITER
(involvement of the members of your social network into the survey)

Recruiting is the process of inviting people from your social network to paticipate in the survey.

If you agree to invite people from your social network to paticipate in the survey, you will be given coupons that need to be distributed. You can give no more than 3 coupons to three representatives of your social network (one coupon per person).

Coupons are tickets to participate in the survey. Therefore, the representatives of your social network, whom you have invited, should bring these coupons with themselves and show them to a survey manager. This is to ensure that they have been invited by you, and that you will be able to receive compensation for doing that.

The compensation is 215 UAH (7$) per one representative of your social network involved into the survey. You will be able to receive compensation in case:

1. your social network representatives meet the eligibility criteria of the research;
2. your social network representatives participated in all survey components (interview and testing).

In order to participate in the survey, the representatives of your social network shall meet the following eligibility criteria:

- male sex
- 16 years old or older at the moment of participation in the survey;
- live/work/study in this city;
- have agreed to participate in all components of the survey: interviewing, blood testing for HIV, viral hepatitis C and syphilis;
- at least one oral or anal sexual contact with a male within the last 6 months.

You have __ days starting from the next day of the survey to recruit members of your social network.

Coupons do not contain information about you or members of your social network. They only contain information on the time and place of the survey conduction.

Annex 27

DATA USE AND CONFIDENTIALITY AGREEMENT
for personnel
(all stages)

Project title: INTEGRATED BIOLOGICAL AND BEHAVIORAL SURVEILLANCE AMONG MEN WHO HAVE SEX WITH MEN IN UKRAINE (2021

Town/city: _____

Organization: _____

Full name: _____

Rols within the project: _____

The information obtained during this is of a highly confidential nature and has given by the study participants on the understanding that it will be treated in the strictest confidence.

Place a check mark next to each clause as well as your signature below to certify that you agree to comply with these rules.

№	Obligations	Notes
1	I will not try to identify study participants	
2	I have understood the data security and confidentiality issues and will adhere to them for the duration of this project	
3	I will not share any data with any researchers other than those working on this research project who have also signed a copy of this form	
4	I will not use or disclose “data set” or “information” for any purpose other than the Research Project identified below, or as required by law	
5	I will not distribute any part of the dataset to anyone who is not part of the Study team, unless required by law	
6	I agree not to attempt to re-identify the source of any information provided	
7	I understand that I am required to securely store all data (paper forms or electronic databases) available for me	

Employee signature: _____

Date: _____

Failure to comply with these rules will result in you being denied further access to data as well as the imposition of any appropriate sanctions, including criminal liability, if provided.

Thank you,
Survey team

Annex 28

UNFORESEEN CIRCUMSTANCES (UC) NOTIFICATION FORM

Town/city: _____

Regional coordinator: _____

Date of UC:		
Detection date of UC:		
The UC has been unpredictable in terms of character, severity, frequency:	Y – yes, N – no	
UC associated with participation in the survey:	Y – yes, N – no	
UC exposes the site or a participant to a greater risk of harm than previously known:	Y – yes, N – no	
If the answers to ALL questions are "Y - yes", report the event as an unforeseen problem the Institutional Review Board and the Administrative Data Source (depending on the situation)		
Briefly describe the UC (if necessary, attach extra pages or accompanying information):		
Describe the harm caused to the participant:		
Describe how the problem was solved:		

Measures taken as a result of UC:	1. No activities	
	2. Revision of Protocol to eliminate the obvious immediate threat to an individual	
	3. Amendments made to the inclusion or exclusion criteria to mitigate newly identified risks	
	4. Implementation of additional procedures for monitoring persons	
	5. Notifications of registered persons	
	6. Termination of survey procedures for registered persons	
	7. Amendments made to the consent documents to reflect newly identified risks at the site or survey level	
	8. Provision of additional information about newly identified risks for those who have already registered for participation	
	9. Other	

UC is a serious undesirable phenomenon:	Y – yes, N – no	
If "Y - yes", please fill out the Reporting Form for serious unforseen events		

Full name: _____

Role within the project: _____

Employee signature: _____

Date: _____

Annex 29

REPORTING FORMS ON SERIOUS ADVERSE EVENTS (SAE)

Town/city: _____

Regional coordinator: _____

Participant ID:		**Age:**		**Gender:**	
Start date of SAE:			**Start time of SAE:**		
Results of SAE:	1. Still occuring				
	2. Resolved without consequences				
	3. Resolved with consequences				
	4. Death				
	5. Still occuring at the time of death, but was not the cause of death				
Date of SAE resolution:			**Time the SAE was resolved:**		
Criterion of severeness:	1. Life threatening				
	2. Required hospitalization				
	3. Disability/incapacity				
	4. Important medical event				
	5. Important non-medical event				
	6. Fatal case				
If case of lethal outcome:	Date of death:			The cause of death:	
Associated with the survey:	1. Associated with (related to participation, there is reasonable assumption that the event has been caused by participation in the survey)				
	2. Not associated				
If SAE is not related to the survey, choose ethology:	1. Background disease, illness or other factors				
	2. Multiple drug intake				
	3. Secondary procedure within the framework of survey				
	4. Accident, injury or other external factors				
	5. Other				
Description/comments (describe SAE, including the chronological clinical manifestations and the development of a serious undesirable event and related signs/symptoms):					

Full name: _____

Responsibilities within the project: _____

Employee's signature: _____

Date: _____

Annex 30

FORM OF THE PROTOCOL DEVIATIONS

Town/city: _____

Regional coordinator: _____

Participant ID:		
Date of deviation:		
Date of deviation detection:		
Description of deviation:		
Full name of the person who identified the deviation:		
Functional role of the person within the survey who identified the deviation:		
Type of deviation:	1. Consent procedures	
	2. Inclusion/exclusion criteria	
	3. Survey procedures	
	4. Survey algorithm	
	5. Laboratory testing procedures	
	6. Reporting of a serious undesirable event	
	7. Use and dissemination of data	
Does the person continue to participate in the survey:		
Does the deviation meet the reporting requirements of the the Institutional Review Board:		
Date of communication to the Ethics Review Board		
Does the deviation meet the requirements on the Administrative Data Source reporting:		
Date of reporting to the Administrative Data Source		
Measures taken to correct the deviation:		
Comments:		

Full name: _____

Role within the project: _____

Employee's signature: _____

Date: _____

Annex 31

WEEKLY REPORTING FORM OF THE NATIONAL COORDINATOR

A0	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	A12	A13	A14	A15	A16	A17	A18	A19	A20	A21	A22	A23	A24	A25	A26	A27	A28	A29	A30	A31	A32	A33	A34	A35	A36	A37	A38	A39
№	City	Date of the field stage start	Planned sampling	Realized sampling, total (number)	Realized sampling (%)	First rapid HIV test (number)	First rapid HIV test + (number)	First rapid HIV test + (%)	First rapid HIV test – (number)	First rapid HIV test inbvailed (number)	Second rapid HIV test (number)	Second rapid HIV test + (number)	Second rapid HIV test + (%)	Second rapid HIV test – (number)	Second rapid HIV test inbvailed (number)	Third rapid HIV test (number)	Third rapid HIV test + (number)	Third rapid HIV test + (%)	Third rapid HIV test – (number)	Third rapid HIV test inbvailed (number)	Anti-Hepatitis C antibodies (number)	Anti-Hepatitis C + antibodies (number)	Anti-Hepatitis C + antibodies (%)	Anti-Hepatitis C - antibodies (number)	Anti-Hepatitis C antibodies invailed (number)	Syphilis (number)	Syphilis + (number)	Syphilis + (%)	Syphilis - (number)	Syphilis invailed (number)	Collected DBS samples (quantity)	Sent DBS samples (quantity)	Rejected DBS samples (quantity)	Number of waves from the 1st seed	Number of waves from the 2nd seed	Number of waves from the 3rd seed	Number of waves from the 4th seed	Date of achieving sample population	Comments/difficulties
1																																							
2																																							
3																																							
4																																							
5																																							
6																																							
7																																							
8																																							
9																																							
10																																							
…																																							
16																																							

Annex 32

WEEKLY REPORTING FORM OF THE REGIONAL COORDINATOR

A0	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	A12	A13	A14	A15	A16	A17	A18	A19	A20	A21	A22	A23	A24	A25	A26	A27	A28	A29	A30	A31	A32	A33	A34	A35	A36	A37	A38
№	Reporting period (date from)	Reporting period (date until)	Number of working days per week	Realized sample in a week	Survey participants (number)	First rapid HIV test (number)	First rapid HIV test + (number)	First rapid HIV test + (%)	First rapid HIV test – (number)	First rapid HIV test inbvailed (number)	Second rapid HIV test (number)	Second rapid HIV test + (number)	Second rapid HIV test + (%)	Second rapid HIV test – (number)	Second rapid HIV test inbvailed (number)	Third rapid HIV test (number)	Third rapid HIV test + (number)	Third rapid HIV test + (%)	Third rapid HIV test – (number)	Third rapid HIV test inbvailed (number)	Anti-Hepatitis C (antibodies number)	Anti-Hepatitis C + antibodies (number)	Anti-Hepatitis C + antibodies (%)	Anti-Hepatitis C - antibodies (number)	Anti-Hepatitis C i antibodies nvailed (number)	Syphilis (number)	Syphilis + (number)	Syphilis + (%)	Syphilis - (number)	Syphilis invailed (number)	Collected DBS samples (quantity)	Sent DBS samples (quantity)	Rejected DBS samples (quantity)	Have you faced any difficult/force majeure situations on the site during the week or not? 1 - yes, 2 – no	If yes, has the appropriate report form been sent to the national coordinator? 1 - yes, 2 - no	Have you had any difficulties working on a tablet, with a program or not? 1 - yes, 2 - no	If yes, what were the difficulties? How have you solved them?	General impressions of the working week on the site
1																																						
2																																						
3																																						
4																																						
5																																						
6																																						
7																																						
8																																						
9																																						
10																																						
…																																						
16																																						

Annex 33

REPORT OF THE REGIONAL TEAM ON THE SURVEY FINDINGS

Town/city: _____

1. COMPOSITION OF THE SURVEY TEAM

№	Functional role within the survey	Full name	Telephone number	E-mail address
1	Regional coordinator			
2	Biological component coordinator			
3	Interviewers (conducting interview/filling in questionnaires)			
4	Medical staff (testing)			
5	Coupon manager			
6	Social worker			

1.1. Has the composition of the regional team changed throughout the survey?

1	Yes
2	No

1.2. If yes, provide information about the replacement of team members

№	Responsibilities within the survey	Full name of the person who worked at the beginning	Full name of the person who continued the work	Reason for replacing a team member
1				
2				
3				
4				
5				
6				

1.3. Have additional team members been involved into working within the survey framework?

1	Yes
2	No

1.4. If yes, provide information about the additional team members involved

№	Responsibilities within the project	Full name of the person	Reason for replacing a team member
1			
2			
3			
4			
5			
6			

2. DIFFICULTIES OCCURED DURING THE FIELD STAGE OF THE SURVEY

May be related to the site, primary respondents, working hours, conducting interview/filling in questionnaires, testing, work on tablets, managing MSM queue, other processes related to the survey realization

№	Responsibilities within the project	Full name	Difficulties that arose while performing functional duties	Ways and means to solve difficulties
1	Regional coordinator			
2	Biological component coordinator			
3	Interviewers (conducting interview/filling in questionnaires)			
4	Medical staff (testing)			
5	Coupon manager			
6	Social worker			

3. GENERAL COMMENTS AND IMPRESSIONS REGARDING THE ARRANGEMENT OF ACTIVITY AND SURVEY CONDUCTION, SUGGESTIONS AND RECOMMENDATIONS FOR PROJECT COORDINATORS

Date of filing the report: _____

Annex 34

REPORT
ON A MONITORING VISIT TO THE SURVEY SITE

Town/city: _____
Date of monitoring visit: _____
Full name of monitoring consultant: _____
The start time of the monitoring visit: _____

1. WORKING HOURS AND LOCATION OF THE SITE

1.1. Specify the site working hours, which ...

1.1.1.	Indicated in the schedule of the national team	
1.1.2.	Indicated in the respondent's coupon	
1.1.3.	The team has been present on the site as a whole and was ready to work with the first respondent	
1.1.4.	The coupon manager started screening of the last respondent	
1.1.5.	The last member of the team left the site	

1.2. If the actual working hours of the site differ from the planned ones (indicated in respondent's coupon), please, specify the reason for changing operational time

1.3. Do team members stay on the site (no respondents present) to work with documentation after working hours specified in the coupon?

1	Yes	
2	No	

1.4. The location of the survey site is the same as it has been identified

1	Yes	
2	No	**How did the survey team (regional coordinator) explain the change of the survey site?**

2. COMPOSITION OF THE SURVEY TEAM

The consultant registers the number of interviewers, medical workers and other team members who are on the site during his/her visit

2.1. The number of team members present on the survey site during the consultant's monitoring visit

№	Responsibilities within the project	Full name	The number of people
2.1.1.	Interviewer		
2.1.2.	Coupon manager		
2.1.2.	Medical worker		
2.1.4.	Regional coordinator		
2.1.5.	Social worker		
2.1.6.	Other team member (please, specify _____)		
2.1.7.	Others present at the survey site, except team members and respondents (specify, please, who exactly _____)		

2.2. The composition and the number of survey team members has changed during your stay on the site

1	Yes	
2	No	**How has the team composition changed? Whether the number of team members increased/decreased? What is the reason for that?**

2.3. How are research team members located on the site? Describe in details, who stays in which rooms and how the rooms are equipped?

2.4. Where do respondents wait for their turn to participate in the survey?

2.5. Do the members of the survey team have personel ID badges?

1	Yes	
2	No	

2.6. Do the members of the survey team leave tablets unattended?

1	Yes	
2	No	

3. THE NUMBER OF RESPONDENTS

3.1. The number of MSM on the site of the survey that...

No.	MSM	Recruiters	Participants	Total
3.1.1.	Visited the survey site during your monitoring visit			
3.1.2.	Had a participant's coupon			
3.1.2.	Tried to participate in the survey without coupon			
3.1.4.	The maximum number of potential respondents during a day of observation, who were simultaneously waiting for their turn			

3.2. Do the interviewers cope with the flow of the respondents being on the site?

1	Yes
2	No

3.3. Is there a need to increase the number of interviewers on the survey site?

1	Yes
2	No

3.4. Specify why you think there is a need/is no need to increase the number of interviewers?

4. RESPONDENTS' SCREENING

4.1. Does a coupon manager conduct a respondent screening prior to their participation in the survey?

1	Yes
2	No

4.2. What questions does the coupon manager ask the respondent to make sure that he belongs to MSM? Specify the question wording

4.3. Do the respondents interviewed meet the survey eligibility criteria?

1	Yes
2	No

4.4. Have there been cases when the respondent was excluded from participation in the survey?

1	Yes	**Why?**
2	No	

4.5. Regardless of whether there have been such cases (item 4.4) during your monitoring visit, ask the coupon manager if they have occurred during the entire time of site's operation? In case of positive answer – how many have there been? For what reasons?

4.6. Is the screening form being filled for each respondent?

1	Yes
2	No

4.9. Are the respondents without a coupon allowed to participate in the survey?

1	Yes
2	No

4.8. Have there been cases when it was impossible to scan the coupon due to external damage of its QR-code?

1	Yes	If yes, describe the coupon-manager's actions in this case? How many of such cases have happened?
2	No	

4.9. Describe the actions of a coupon manager if case the respondent comes with a coupon issued at the same day

4.10. Does the coupon manager ask the respondents about the person who gave them a participant coupon (acquaintance or stranger)?

1	Yes
2	No

4.11. Have there been cases when the participant did not answer the question on who had given him a coupon or gave uncertain answer, but is still admitted to the survey participation?

1	Yes
2	No

4.12. Which toolkit does a coupon manager use – paper or electronic one (tablet)? If a paper form is used, ask why?

4.13. Does the coupon manager issue a checklist to the respondent for tracking the survey algorithm?

1	Yes	Who issues it? Does the coupon manager sign it after the respondent's screening?
2	No	

5. INFORMED CONSENT

5.1. The informed consent is read out to the respondent or provided for self-reading. In case of reading out, whether the full text is voiced or not? If not the full text, what information is read to the respondent?

5.2. Does the coupon manager give the respondent one copy of informed consent?

1	Yes
2	No

6. SURVEYS

6.1. Describe the facilities of the interview venue (separate survey room; one room equipped with separate places for interviewing; in the street, etc.)

6.2. Is the confidentiality of the survey being ensured? Describe where the interviewers are located?

6.3. How much time, on average, does the interviewer spend on interviewing one MSM?

6.4. Have you been allowed to attend an interview?

1	Yes	**Does the interviewer ask all the questions from the questionnaire; Are the questions being paraphrased or sound exactly as they are formulated in a questionnaire? In case of paraphrasing, whether it's systematic or does it happen only in some cases?**
2	No	**Who exactly has initiated the refusal?**

6.5. Which toolkit does the interviewer use in his/her work? *(be sure to specify the means of conducting survey: on a tablet or using paper questionnaire)*

6.6. Does the survey team work with tablets online or offline ?

6.7. How many tablets are used on the site?

6.8. Do interviewers sign the checklist after completing an interview?

1	Yes
2	No

7. TESTING

7.1. Is the confidentiality ensured when reporting test results to respondents?

1	Yes
2	No

7.2. Is blood testing conducted before or after interviewing?

7.3. Whether pre-test counseling (inform about HIV transmission and safe behavior) and post-test counseling are conducted for the respondents? *(ask the respondents upon their leaving the doctor's office)*

7.4. Do the respondents with positive test results receive a referral for test confirmation and HIV treatment? *(check the records in the Logbook for the referrals to the faciity that provides HIV treatment)*

1	Yes
2	No

7.5. How much time on average does the medical worker spend performing biological component with one respondent (pre-test counseling, testing, post-test counseling, DBS)?

7.6. Are HIV positive respondents being referred to case-management?

1	Yes
2	No

7.7. Does the medical worker sign the respondent's checklist after completing the test?

1	Yes
2	No

7.8. Under what conditions DBS is being dried? Describe in detail or take a picture

7.9. Check with medical worker, in which cases ...

7.9.1.	The second rapid HIV test is done	
7.9.2.	The third rapid HIV test is done	
7.9.2.	DBS sampling is done	

7.10. Where are respondents with a positive test result for anti-hepatitis C antibodies being referred to for result confirmation? Do they get vouchers for free testing?

7.11. Where are respondents with a positive test result for syphilis being referred to for result confirmation? Do they get vouchers for free testing?

7.12. Ask the respondent upon leaving the physician's office (before his leaving the site) whether the medical worker has given him a medical certificate with the test results or not? Say the following, "I am not asking about your HIV test result. I just want to know whether you received a medical certificate with your test results or not?"

8. SURVEY COMPLETION, RECEIPT OF COUPONS FOR RECRUITING

8.1. Does the coupon manager verify the signatures of team members in the checklist?

1	Yes
2	No

8.2. Do the respondents receive compensation for participating in the survey?

1	Yes	**What is the amount of compensation?**
2	No	

8.3. Do all participants receive the same amount of compensation?

1	Yes
2	No

8.4. Is the data on remuneration payments being recorded in the registration Logbook?

1	Yes
2	No

8.5. Does the respondent put his signature in the compensation Logbook?

1	Yes
2	No

8.6. Does the coupon manager give the coupons to MSM respondents for recruiting other peers?

1	Yes
2	No

8.7. How many coupons does the coupon manager give to a respondent for recruiting?

8.8. Have the coupons been scanned before their issuing to the respondent?

1	Yes
2	No

8.9. What instructions does the coupon manager give to the respondent before granting coupons?

8.10. Does the coupon manager give to the respondent an informational leaflet with the description of eligibility criteria and instructions for the recruiter on who and how to recruit?

1	Yes
2	No

8.11. Have there been cases of repeated participation of the same respondent in the survey?

1	Yes
2	No

9. DOCUMENTATION ANALYSIS

9.1. The number of…

№	Documentation	During the monitoring visit	Total
9.1.1.	Respondents listed in the Logbook for compensation		
9.1.2.	Forms of testing results		
9.1.2.	Informed consents		

9.2. Does the healthcare worker enter the testing resultsfrom paper forms into electronic form at the end of the day?

1	Yes
2	No

9.3. Where and when does the healthcare worker enter medical forms to the electronic form ?

9.4. Indicate the number of unused and used materials ...

№	Materials	Used	Unused
9.3.1.	First test for HIV – HIV-1/2, Rapid Test for Antibody to HIV, Colloidal Gold Device		
9.3.2.	Second test for HIV – HIV-1/2.0, First Response v.3.0 Cards Kit		
9.3.3.	Third test for HIV – HIV-1/2, Bioline 3.0		
9.3.4.	First test for hepatitis C – Hepatitis C Rapid Diagnostic Test, Bioline HCV		
9.3.5.	First test for syphilis – Syphilis Rapid Diagnostic Test, Bioline 3.0		
9.3.6.	DBS card		

9.5. Indicate how much time ...

9.4.1.	The site had already been operating at the time you recorded the quantity of unused medical materials	_____min. _____ hour
9.4.2.	The site still has to operate in accordance with the approved survey schedule at the time you recorded the quantity of unused medical materials	_____min. _____ hour

9.6. Specify the conditions in which unused test systems are stored (for example, the approximate temperature of air, whether there is working heater, streaming sunlight, test systems are unpacked in advance, etc.)

10. ADDITIONAL COMMENTS

10.1. Please, supplement the mentioned information with comments on the peculiarities of the study implementation in this city, your impressions on the organization of the process and the work of the team

The time of the monitoring visit completion: _____

Consultant's signature: _____

Annex 35

FACT SHEET
ON UNDERSTANDING RECENT AND LONG-TERM HIV INFECTION

Recent HIV infection

Recent HIV infection means a person likely got HIV within the past one year.

People with recent HIV infection have high amounts of HIV in their blood. Having more virus means that it is easier to pass on infection to others. HIV medications (antiretrovirals or ARVs) lower the amount of HIV in your body. ARVs help you to stay healthy. ARVs make it less likely for you to pass the infection to others, including unborn and breastfeeding infants and sex partners. ARVs need to be taken every day or as prescribed by a doctor for your health. This will also lower the risk of passing HIV. There is a small (one in ten) chance that someone who got HIV more than one year ago will test as if they have a recent infection. The test cannot tell exactly when you got HIV. The test cannot tell you who passed the infection to you.

Long-term HIV infection

A long-term HIV infection means a person likely got HIV more than one year ago. A person with long-term HIV infection can still pass HIV to other people. People with any HIV infection should start and stay on HIV medications (ARVs) as prescribed by your doctor for your health. ARVs lower the risk of passing HIV to others. There is a chance that someone who got HIV within the past one year will test as if they have a long-term infection. The test cannot tell exactly when you got HIV. The test cannot tell you who passed the infection to you.

Annex 36

INFORMATION REGARDING PrEP

PrEP (Pre-exposure prophylaxis) – is the use of medication to reduce the risk of HIV infection by people who do not have HIV (are HIV negative), however are still at higher risk of becoming infected.

This type of preventative measure is recommended for people from so-called seriodiscordant couples, where one partner lives with HIV and the other is HIV-negative.

You can get consultations about PrEP from doctors and / or other professionals (i.e. NGO social workers). After a joint assessment of risks and needs, you can decide for yourself the need for this type of preventative measure.

If you wish to receive pre-exposure prophylaxis, you will need to undergo a medical examination:

- An HIV test. HIV testing should be performed prior to starting PrEP;
- • Determination of creatinine levels to assess renal function. PrEP may have little effect on kidney function, however studies show that after you stop medication, kidney function returns to normal;
- • A Hepatitis B test. It is important to remember that there is a hepatitis B vaccine.
- • Other tests (for hepatitis C, sexually transmitted infections, etc.) are recommended.

Currently, in most countries and in Ukraine, the recommended regimen of PrEP is daily. However, according to the new WHO recommendations, another admission scheme has been developed - on demand. However, the scheme of admission on a daily basis is recommended in Ukraine. Its formula: 7 days prior + X days + 28 days after, where X days depends on a person's desire and need for PrEP.

You can get pre-exposure prevention (PrEP) in every region of Ukraine (in government-controlled areas).

Detailed information can be obtained by contacting specialists from non-governmental organizations or AIDS centers, as well as on the website of the Pulic Health Center (https://prep.phc.org.ua/).

You can also call the NATIONAL HIV / AIDS HOTLINE 0-800-500-451 for information.

Annex 37

DATA REQUEST FORM

1. GENERAL INFORMATION		
1.1. Principal Investigator surname:		
1.2. Principal Investigator name:		
1.3. Principal Investigator middle name:		
1.4. Principal Investigator position:		
1.5. Organization Type:		
1.6. Name of the Principal investigator's organization:		
1.7. Principal investigator's mailing address:		
1.8. Principal Investigator Email:		
1.9. Principal Investigator phone:		
1.10. Requester surname:		
1.11. Requester name:		
1.12. Requester middle name:		
1.13. Requester position:		
1.14. Organization Type:		
1.15. Name of the Requester's organization:		
1.16. Requester's mailing address:		
1.17. Requester Email:		
1.18. Requester phone:		
1.19. Information about the researchers involved in the project *(name, position, organization, contact information):*		
1.20. Names of organizations involved in the project *(contact information):*		
1.21.	Description of relevant experience requestor:	
2. PROJECT INFORMATION		
2.1.	Project name:	
2.2.	Type of project *(research, publication, poster, abstracts, etc.)*	
2.3. Planned and actual start date of the project:		
2.4. Planned project completion date:		
2.5.	Purpose of the project:	
2.6.	Objectives of the project:	

2.7.	Project hypotheses and assumptions *(optional):*	
2.8.	Expected project results:	
2.9.	Rationale for the request:	
2.10.	Expected benefits for the project from the requested data:	
2.11.	Source of project financing:	
2.12.	Name of the project sponsor:	
2.13.	Contact person from the project sponsor:	
3. INFORMATION ON THE REQUESTED DATA		
3.1.	Name of requested data:	
3.2.	Type of data requested:	
3.3.	Format of data requested:	
3.4.	Description of the requested variables *(if dataset is requested, describe what variables are required):*	
3.5.	Inclusion and exclusion criteria:	
3.6.	Analysis plan for the requested data *(describe the analysis plan, including the one-dimensional, two-dimensional and multidimensional approaches, statistical models, software to be used):*	
3.7.	Methods of analysis of the requested data:	
3.8.	Scheduled publications based on requested data:	
3.9.	Planned start date for analysis:	
3.10.	Planned first ready draft date:	
3.11.	Intended date of submission to the IRB:	
3.12	Intended date of use of the analysis results *(date of submission to the conference, to the journal, presentation of the report, etc.):*	

I confirm that I have read and understood the request form.

I confirm that the information I provided in the request is true and correct in every respect.

I confirm that the information received will only be used for the purposes stated in the request.

I confirm that only the persons named in the request will have access to the data.

I undertake not to disclose or publish data in any form or format without the prior permission of PHC. I understand that a breach of this obligation may result in the rejection of future data requests from me or from the organization I represent.

Data	**Signature**

Filled by representatives of PHC: IBBS Principal Investigator

Request Number:	
Request Status:	
Request Comments:	
Full name of IBBS Principal Investigator:	
Signature of IBBS Principal Investigator:	
Data:	

Annex 38

BBS MSM 2024 UKRAINE PRIORITY RESULTS TABLE

Variable	n	% (95% CI)
Age		
16-19		
20-24		
25-29		
30-34		
35-39		
>40		
Used a condom at last sex with another man		
Received free condoms in the last 12 months		
Tested for HIV in the last 12 months		
Heard about pre-exposure prophylaxis		
Taken pre-exposure prophylaxis in the last 12 months		
Time since last HIV test		
0-6 months		
7-12 months		
>12 months		
Started ART but no longer taking ART		
Had ever HIV viral load measured		
HIV prevalence		
Aware of HIV-positive status (1st 90)		
Aware of HIV-positive status and on ART (2nd 90)		
On ART and virally suppressed (3rd 90)		
Viral suppression among all HIV+		
Anti-TP prevalence		
Active syphilis prevalence (among those reactive for anti-TP who were tested)		
Anti-HCV prevalence		
Prevalence of HCV RNA (among those who were tested)		
Population size estimate		

Annex 39

QUESTIONNAIRE FOR A FORMATIVE STUDY AMONG MSM

A. **City:**
B. **Date:**
Interviewer! In case the expert does not belong to an NGO that deals with the MSM, questions C, D are not asked. Proceed to question 1.
C. ***Name of organization:***

_____

D. ***Expert position:***

_____

Do you know MSM who:	Yes	No
1. live or work in this city	1	2
2. know many other MSM (at least 7)	1	2
3. are communicative (communicate a lot with others)	1	2
4. would be interested in taking part in the study	1	2

5. Do you know, / one or more such men?
1. one
2. several_____(specify number)
3. no, I don't know such men

6. Would you be willing to leave us contact information for this man/these man for research purposes?

_____
_____
_____
_____

7. Do you know MSM who work/live in different parts of the city?
1. Yes
2. No

8. Do you know MSM who differ in their socio-demographic characteristics (e.g., some are older, some are younger, some provide transactional sex, etc.)?
1. Yes (describe them)

_____
_____

2. No

9. Do you know high-income (financially secure) MSM?

1. Yes 9.1. What might be the motivation for their participation in the study?

_____
_____
_____

2. No

10. Do you know MSM in your city under the age of 18?

1. Yes 10.1. What might be the motivation for their participation in the study?

_____
_____
_____

2. No

11. What are the most effective ways to access the MSM?

(DO NOT RECOMMEND LET THE RESPONDENT ANSWER FOR HIMSELF: e.g., through employees of community organizations? search for ads in local print publications/Internet? other ways?)

_____
_____
_____

12. What would encourage MSM to involve other MSM in the study?

_____
_____
_____

FOR MSM ONLY

13. Would you (or your friends) be willing to take this survey?

1. Yes (why?)

_____

2.No (why?)

_____

14. Would you agree to recruit other MSM to participate in this survey?

I. Yes → 14.1 How many coupons out of three could you give out to other
2. No MSM so that they could participate in this study?
(Circle the answer the expert says!)
1 2 3

15. What do you find most/least interesting about this survey?

_____
_____
_____

16. What would encourage MSM to participate in the study (rewards, condoms, booklets, etc.)

_____
_____

17. In your opinion, what time of day would be most convenient for MSM to participate in the study?

_____
_____

18. And what days of the week are convenient to participate in the study - any days or only certain weekdays or weekends?

_____
_____

19. What should be the location of the survey? And in what part of town is the best place to set up an MSM survey point?

_____
_____

20. Do you think HIV testing will be perceived by MSM as an additional incentive to participate in the study?

1. Yes, 2. No 3. Difficult to answer (do not read out)

21. What do you think might prevent you or other MSM from participating in the study? To what extent does the risk of mobilization affect the willingness to participate in the study? To what extent does the security situation (e.g., Russian shelling and air raids) influence your willingness to participate in the study? What can be done to reduce the impact of these factors?

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

22. In the course of the study, methods that depend on the availability of mobile phones among participants may be used to estimate the size of the MSM group in the city. Do MSM in this city have multiple phone numbers?

1. Yes, 2. No 3. Difficult to answer (do not read out)

23. Do they change phone numbers often?

1. Yes, 2. No 3. Difficult to answer (do not read out)

24. Are they able and willing to list their peers' phone numbers (not the whole number, just a part of it (4 digits))?

1. Yes, 2. No 3. Difficult to answer (do not read out)

25. Can you think of any MSM who would make a good primary respondent? (Primary respondents are respondents who should be willing to take an active part in recruiting secondary respondents, interact with other MSM, have high social status, good reputation and are trusted, people who are considered "informal leaders" in their circle of friends and acquaintances, they can convince others to take part in the study, and attract the next participants, etc.)

1. Yes (describe them) _____
2. No

26. From your perspective, what is the best way to find MSM who would make good primary respondents for our study?

_____
_____
_____

27. Can you think of any MSM who would be able to recruit other high-income MSM?

1, Yes Can you provide us with contacts for such an MSM?

1. Yes (give name and phone number)

   _____

2. No

28. Can you think of any MSM who provide sexual favors for a fee?

1. Yes Can you provide us with contacts for such an MSM?

   1. Yes (give name and phone number)

      _____

   2. No

29. Who else would you recommend we contact to get information on the questions in our questionnaire?

_____
_____
_____
_____

Thank you for your participation!