INDEX PARTICIPANT
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Public Health Management Corporation
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Public Health Management Corporation
Voluntary Consent to be in a Research Study and
HIPAA Authorization to Use and Share Your Protected Health Information

Name of Study: COVID-19 Self-Testing through Rapid Network Distribution **(Index Participant)**

Important Things to Know About This Study

- We are asking you to be in a research study. Your participation is voluntary. If you sign this form, you are agreeing to be in this study. You should not sign this form unless you are sure you want to be in this study and all of your questions about this study have been answered.
- The purpose of this study is to determine how to help more people who need a COVID-19 test get tested.
- If you agree to be in this study, you will be asked to help others in your social network (friends, family) to get tested for COVID-19 over the next two months. You will be given either referrals to clinic sites for testing, or home self-test kits. We will send you a survey in two months.
- This study involves very few risks. We have plans in place to lower these risks.
- You may not benefit from being in this study.
- We will get information about you for this study. We have plans in place to keep your information confidential.
- This form will explain all of this to you in more detail.

1. What is the purpose of this study?

Public Health Management Corporation (PHMC) is doing this study to learn more about strategies to increase COVID-19 testing.

2. Who is in charge of this study?

This study is being led by:

- Dr. Robert Gross at University of Pennsylvania
- Dr. Karen Dugosh at PHMC
- Dr. Cedric Bien-Gund at University of Pennsylvania

These groups are also working with us on this study:

1) Congreso Health Center
2) PHMC Care Clinic

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3) Mary Howard Health Center
4) Rising Sun Health Center
5) PHMC Health Connection

3. Why am I being asked to be in this study?

We are asking you to be in this study because:

- You are at least 18 years of age
- You have a working phone number

You cannot be in this study if:

- You have participated in this trial previously or received COVID-19 testing as part of this study
- You have been infected with COVID-19 in the past 90 days

4. Who will be in this study?

About 1,048 people will be in this study.

5. How long will I be in this study?

You will be in this study for 12 weeks. If you test positive for COVID-19 during the study at one of the study sites, you may be contacted to participate in another part of the study. You may drop out at any time.

6. What are you asking me to do?

If you agree to be in this study, you will be asked to:

1) Give out COVID-19 test referrals or home test kits. You will be asked to encourage your friends, family, and others you are close to that are at risk of COVID-19 to get tested for COVID-19. You will be given information on how to minimize your risk of spreading COVID-19.

2) Answer surveys. You will be asked to do 2 surveys about yourself, medical history, and your experiences with COVID-19 testing. These surveys will be done in-person at a study site or over the phone. You will be asked to do these surveys today and 8 weeks from now. If you test positive for COVID-19 during the study and agree to take part in another part of the study, you will be asked to complete a third survey that asks similar questions. Each survey will take about 15-20 minutes to complete.

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3) Participate in an interview. You may be asked to do an interview in 8 weeks. We will ask you questions about your experiences giving COVID-19 test information, changes in your life due to COVID-19, and your social network. There will be one potential interview. The interview will be done over the phone. The interview will take about *one hour* to complete.

4) If you are tested for COVID-19 during the study at one of the study sites and have a positive result, you will be asked to take part in another part of this study of people with COVID-19.

5) Give us some personal information. We will ask for information such as:
   A) *Age, gender, sex, race, ethnicity, language, education, and zip code*
   B) *Medical history, health insurance status, employment information*
   C) *Household information and your social network.*
   D) *COVID-19 exposure, prior COVID-19 testing, information about COVID-19, and symptoms.*

   We will use this information to describe the people in this study as a group.

6) Give us your contact information. We will ask for:
   A) *Phone number, email, address*

   We will use this information to contact you to do a follow-up survey 8 weeks from now and to speak to you about an additional study if you test positive for COVID-19.

7) Be randomly assigned to Group A or Group B. Random assignment is like flipping a coin. It makes each person have an equal chance of being in each group. You and the research team do not decide which group you are in. Group A will get COVID-19 home test kits, and Group B will get referrals for COVID-19 testing.

   A) If you are in **Group A**, you will:
      - Be asked to give out COVID-19 home test kits to people you interact with, such as people you live with, work with, or spend time with, who are at risk of COVID-19.

   B) If you are in **Group B**, you will:
      - Be asked to give out COVID-19 test referrals to people you interact with, such as people you live with, work with, or spend time with, who are at risk of COVID-19.

7. Will my information be kept confidential?

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Yes, we will do our best to keep your personal information confidential. We cannot promise total confidentiality. We have done several things to protect your information:

1) We will only share your information with people who need to use it for this study.
2) Any information kept on a computer will be in a password-protected file. Only research staff on this study will know the password.
3) Any paper information will be kept in a locked filing cabinet. Only research staff on this study will have access to this cabinet.
4) Your research records will not have your name on them. We will use a code number instead. The code number will be kept secure and separate from your name. Only research staff on this study will have access to the code numbers and names.
5) The U.S. Government gave us a Certificate of Confidentiality (CoC) for this study. The CoC helps protect your identity and research information from people and groups who are not a part of this study. We cannot be forced to share your information, even under a court order. You can still share information about yourself or tell others that you are in this study.

Exceptions to confidentiality. There are times when we will break this confidentiality agreement with you:

1) Any information about child abuse or intent to harm self or others will be reported to authorities, as required by law.
2) We will also break this agreement if you are having a medical emergency, or if your safety is at risk.

8. Will my research information be used or shared for future research studies?

We will keep information that can identify you (like your name and date of birth) secure and separate from your research information. We may use or share your de-identified research information for future research studies without asking for your consent again.

9. What are the possible risks of being in this study?

1) There may be a breach of confidentiality. While a breach of confidentiality to records containing identifiable information is possible, the probability is low given the numerous safeguards we have taken to protect your information. We will do our best to keep your information confidential. It is still possible that your information may be seen or heard by someone who should not see or hear it.

   We have taken these steps to lower this risk:
   - The surveys you complete for this study will not have your name on them.

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- We will keep your personal information separate from your study information.
- All paper information will be kept in a locked filing cabinet at 1500 Market Street. Only research staff on this study will have access to this cabinet.
- All electronic information will be kept in a password-protected computer. Only research staff on this study will know the password.
- We will ask everyone in the focus group to keep everything confidential.
- When we try to call you, we will say we are calling about a health survey. We will not talk about this study until we know it is you on the phone.

2) Some parts of this study may make you feel uncomfortable, upset, or stressed. You may feel uncomfortable, upset, or stressed:
   - During the surveys or interview
   - Talking about COVID-19 with other people

   We have taken these steps to lower this risk:
   - You can talk with research staff at any time.
   - You can skip any survey questions you do not want to answer.

3) Possibility of or perceived invasion of privacy to the participant or their family. You may find the questions in this study to be invasive.
   - You can skip questions that you do not wish to answer.
   - We will keep your personal information separate from your study information.

10. What are the possible benefits of being in this study?

You may not get any benefits from being in this study. The information we get from this study may help us find ways to help people get tested for COVID-19 and health care in the future.

11. Do I have to pay to be in this study?

No, you do not have to pay extra to be in this study. All of the services you will get during this study are the same as the services you will get if you choose not to be in this study. Your services will be billed to you and/or your insurance company like normal. You will not be charged extra if you agree to be in this study.

12. Will I be paid for being in this study?

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We will pay you for completing study tasks. In total, you can earn at most $30 for completing these tasks:

- You will receive $15 after you complete the baseline survey and enroll in the study.
- You will receive $15 after you complete the follow-up survey in 8 weeks.

- We will interview some participants, and you may be asked to do an interview. If you agree, you will receive $50 for doing it.

You will be paid with a prepaid gift card. If you drop out of the study or are asked to leave the study, you will still be able to keep the money you were given.

13. Do I have to be in this study?

No, you do not have to be in this study. No one will treat you differently if you do not want to do this. You will not get in trouble if you do not want to be in this study. If you do not want to be in this study, tell us and do not sign this form. If you want to be in this study, tell us and sign your name at the end of this form.

You can say "yes" now and change your mind later. If you do not want to be in this study anymore, you can tell Dr. Gross. Dr. Gross is the Principal Investigator (the person in charge of this study). Dr. Gross's phone number is 215-898-2437 and their email address is grossr@pennmedicine.upenn.edu. We will not ask you for more information, but we will keep the information we got before you changed your mind.

14. What other choices do I have if I choose not to be in this study?

If you do not want to be in this study, you will still be able to get the same services and care. People you are close with will still be able to get tested for COVID-19 as they normally would.

15. Will I be contacted in the future about this study?

We will contact you in the future if:

- There is new or important information that may make you change your mind about being in this study.
- We learn important information about your health, safety, or rights after the study ends.

We would like your permission to contact you in the future for this reason:

- To ask you to give more information for this study. The information we may ask for in the future may be similar to what we ask for now.

You can decide now if you want to be contacted in the future for this reason. If you agree now, you can change your mind later.

Please write the initials of your name next to your choice:

_____ I agree to let someone from this study contact me in the future.

_____ I do not agree to let someone from this study contact me in the future.

16. Will information about this study be available to the public?

Information about this research study can be found on www.ClinicalTrials.gov. This web site will not have information that can identify you. You can search for this project on this web site at any time.

17. Who can I call about my rights as a participant in this research study?

The Institutional Review Board (IRB) makes sure that this study is being done right. You can call the PHMC IRB at 1-800-335-9874 or email ResearchCompliance@phmc.org.

- You have questions about your rights as a study participant.
- You want to make a complaint about this study.
- You get an injury from being in this study.

If you have questions about this study, you can contact Dr. Gross. Dr. Gross's phone number is 215-898-2437 and their email address is grossr@pennmedicine.upenn.edu

HIPAA Authorization to Use and Share Your Protected Health Information

Important Things to Know About This Authorization

- Some of the information we are asking to get, use, and share is called "Protected Health Information" (PHI). PHI is health information that can identify you.
- PHI is protected by a law called "The Health Insurance Portability and Accountability Act of 1996" (HIPAA). This means we need to follow certain rules to use or share PHI.
- Information about you and your health is personal and private, so we cannot use or share this information without your permission.
- We are asking you to give us permission to use and share your PHI for this study.
- The rest of this form will explain all of this to you in more detail.

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1. What PHI will be used and shared for this study? How will PHMC get my PHI?

We will ask you to share the following PHI in the surveys and interviews:

1) *Name, date of birth, home address, phone number, email address,*
2) *Medical record number (MRN)*
3) *Race/Ethnicity, sex at birth, education, housing, employment, insurance*
4) *Height and weight*
5) *Medical history, including substance use, alcohol use*
6) *Prior infections, including Hepatitis B, Hepatitis C, and HIV*
7) *Mental health history*
8) *Exposure to COVID-19, symptoms, and prior COVID-19 testing*

If you are tested for COVID-19, we will get your test results from the medical chart.

2. Why is my PHI being used and shared?

We will use and share your PHI to find out if our program is effective at increasing COVID-19 testing in the community.

3. Who at PHMC will use and share my PHI?

Only these people or groups at PHMC will use or share your PHI:

A) People or groups who work on this study:
- Robert Gross, Karen Dugosh, Cedric Bien-Gund, and their study team

B) People or groups who make sure this study is being done right:
- The PHMC Institutional Review Board (IRB)

4. Who outside of PHMC will use and share my PHI?

For this study, only these people and groups will use and share your PHI:

A) Other people or groups who are in charge of this study:
- C-STRAND investigators who work for PHMC and the Univ. of Pennsylvania

B) Other people or groups who make sure this study is being done right:
- An independent Data and Safety Monitoring Board (DSMB)

Your PHI may not be protected by privacy laws after we share it with these people and groups.

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5. How long will my PHI be used?

We will get, use, and share your PHI from now until the study ends, unless you change your mind. After the study is done, we will stop getting, using, and sharing your PHI.

6. What happens if I do not give you permission to use my PHI?

If you do not give us permission to use your PHI, you cannot be in this study. You will still be able to get health care through PHMC.

7. What happens if I give you permission to use my PHI, but change my mind later?

You can change your mind at any time. You will not be treated differently. If you change your mind, send a letter to Dr. Gross saying you do not want us to use your PHI anymore. You should send letters to this address:

Dr. Robert Gross c/o Dr. Karen Dugosh
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When you cancel your permission, you will still be a part of this study. We will stop collecting your PHI after we get your letter. We may still use and share the PHI we collected before we get the letter to make sure the study is being done right. We will continue to collect other information that is not PHI.

Documentation of Informed Consent and HIPAA Authorization to Use and Disclose Your PHI

- I have read, or been read, this form.
- All of my questions were answered.
- I understand why I am being asked to be in this study and what I will be asked to do.
- I understand why my PHI will be used and how it will be used for this study.
- I agree to be in this study and I give PHMC permission to get, use, and share my PHI for this study.
- I will get a signed copy of this form to keep.

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Your Name (please print)	Signature	Date
Research Staff Obtaining Consent	Signature	Date

Optional Additional Participation in National Study of COVID-19

Are there additional ways I can participate in the study?

Yes. The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP, we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

What will you ask of me?

If you decide to join this study, we will gather information about you. We will gather some of the data from you directly. We will gather some of the data from other places.

- Information that you have shared with the study researchers will also be shared with the RADx-UP program, including basic information such as, but not limited to, your name, date of birth, address, contact information, ethnicity, gender, language, health insurance status, disability, job, and household information including address history.
- We will ask you information about your health, education, family, home, relationships, and social life, among others.
- We will ask about your medical history and if you have or have not had vaccines and why.

What will you do with my data?

They will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.
The DCRI will build two RADx-UP databases (systems that hold electronic information).
The first database will only hold information that can identify you (called identifiable information). Examples are your name, address, email, and gender.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.

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- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.

The second database will not hold information to identify you. It will hold all the non-identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

OPTIONAL (please check one box only):

☐ I agree to let the DCRI collect my **non-identifiable** information and the following **identifiable** information: name, address, contact information, and date of birth, as stated above.

☐ I agree to let the DCRI collect my **non-identifiable** information and **zip code**, but no other **identifiable** information as stated above.

☐ I agree to let the DCRI collect my **non-identifiable** information, but **not** my zip code and no other **identifiable** information as stated above.

☐ **I do not agree** to let the study team share with the DCRI any of my information as stated above.

Signature: _____ Date: _____

I agree to be contacted for future research as stated above.

_____ Yes Initials

_____ No Initials