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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK
[INSERT NAME OF SITE]

PATIENT PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: 'Healthy Living Study'
Protocol #: CTN-0101
Sponsor: National Institutes of Health (NIH)
Lead Investigator: Jennifer McNeely, MD, MS
NYU School of Medicine
550 1st Avenue
New York, NY 10016
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Site Principal Investigator: [INSERT NAME OF SITE PI]
Institution: [INSERT NAME OF PARTICIPATING INSTITUTION]
Address: [INSERT ADDRESS OF PARTICIPATING INSTITUTION]
Telephone: [INSERT PHONE NUMBER OF SITE PI]

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to participate in the *Healthy Living Study* that [INSERT CLINIC NAME] is taking part in. This study seeks to understand whether counseling by nurses and telephone health coaches can help patients to change their health behaviors, such as exercise, nutrition, and use of tobacco, opioids, alcohol, and other substances. Approximately 300 patient participants will be enrolled in this study at five research sites, with about 75 from this site.

The following table contains key information to assist you in understanding why you may or may not want to participate in the research study.

Purpose	The purpose of this study is to understand whether counseling by telephone health coaches and nurses can help patients adopt healthier behaviors.
Voluntary Participation	Your decision to be in this study is your choice. You may decide not to participate or you may discontinue your participation at any time during the study, without penalty or loss of benefits or medical care to which you are otherwise entitled.
Withdrawal	If you decide to participate in this study and then change your mind, you can leave the study at any time without penalty and without giving a reason.
Length of Participation	Your participation in the study will last approximately 12 months.
Procedures	The procedures in the study will depend on which group you are assigned. All participants will: • Complete health behavior questionnaires at your baseline visit (by computer, phone,

	and/or in person), and at approximately 3, 6, 9, and 12 months afterwards (by computer and/or phone). • Provide a urine sample at baseline, and at approximately 6 and 12 months. • Receive health advice from a short video. • Respond to a brief survey that you will receive via email or text message once a month. You may complete this survey on any internet enabled device. Depending on your group assignment, some participants may also: • Receive health advice from your primary care provider • Complete 2 health coaching sessions via telephone or video chat approximately 2 and 6 weeks after enrollment. Some participants may be offered participation in 4 additional health coaching sessions. • Meet with a Nurse Care Manager throughout the study for education on health-related behaviors.
Risks	Risks associated with participation are minimal. It is not anticipated that there will be any injury or adverse reactions caused by the study intervention.
Benefit	As a result of your participation in this study, you could potentially benefit, but there is no guarantee. However, what is learned may help people in the future with improving healthy behaviors.
Alternative to Study Participation	The alternative to participating is to not participate. If you do not want to be in this study, your eligibility for the medical care and services at this clinic will not be affected. You can still get services to which you have access and are otherwise entitled.
Costs	There will be no costs for you to participate.
Compensation	If you complete all study activities, the maximum amount you may be compensated is $680.
Confidentiality	To the extent allowed by law, every effort will be made to keep your personal health information and study information confidential.

This overview does not include all of the information you need to know before deciding whether to take part. Additional details are given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

Informed Consent Form

INTRODUCTION

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the research staff to explain anything in this form or about the study that is unclear. Please take time to read this information carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in the research study, you must sign this consent form.

This is a multi-site study supported by the National Institutes of Health (NIH). Dr. Jennifer McNeely at New York University School of Medicine and Dr. Jane Liebschutz at University of Pittsburgh School of Medicine are the national Lead Investigators of this study. [NAME OF SITE PI] is the Principal Investigator for this study at [NAME OF SITE].

DISCLOSURE OF FINANCIAL INTERESTS

The National Institutes of Health (NIH) is providing funds to the [INSERT NAME OF SITE] to conduct this multi-site study.

PURPOSE OF THE STUDY

This clinic and your primary care provider are taking part in a *Healthy Living Study*, which seeks to understand whether nurses and telephone health coaches can help patients change their health behaviors, such as exercise, nutrition, and use of tobacco, opioids, alcohol, and other substances.

NUMBER OF PARTICIPANTS AND LENGTH OF STUDY

Your participation in the study will last approximately 12 months. Approximately 300 patient participants will be enrolled in this study at five research sites, with about 75 from this site.

STUDY PROCEDURES

If you choose to be in the study, you will be asked to sign this consent before you begin the study. The baseline visit will last approximately 30 minutes to 1 hour. After that, you will be asked to participate in additional activities, detailed below, over the course of approximately 12 months.

Primary care providers have been randomly assigned to one of two groups (Group A and Group B, as described below). The providers are assigned to their group by chance, like flipping a coin. The study activities you participate in will depend on the group to which your provider is assigned. You are not able to choose which group you are in. You will not know ahead of time the group assignment of your primary care provider.

No one outside of the research staff will see your answers to any surveys or interviews, or the results of your urine tests, with the following exception:

- For Group A participants, results of the Healthy Living Survey that you completed as part of screening for this study will be shared with your primary care provider, nurse care manager, and telephone health coach. No other survey data or results will be shared with clinical staff during the study.

The following is the schedule of study activities and what will be done for each group.

Study Activity	**Group A**	**Group B**
Baseline Visit, approximately 30 minutes to 1 hour	Complete health behavior questionnaires. Provide a urine sample. Receive educational materials and watch a brief video.	Complete health behavior questionnaires. Provide a urine sample. Receive educational materials and a watch a brief video.
Primary Care Provider advice (3-5 minutes)	Primary care provider receives your responses to the Healthy Living Survey (screening survey) and provides you with advice based on the results.	Not applicable.

Meet with the Nurse Care Manager (throughout study period)	Meet (in-person or via phone or video call) with the Nurse Care Manager to discuss changes to health behaviors.	Not applicable.
Telephone Health Coaching, approximately 20-30 minutes	Two sessions with a telephone health coach, scheduled within the first six weeks after the Baseline visit. During these calls, you will address issues related to your health, including symptom management, behavior change, and quality of life. Some participants will be offered participation in 4 additional telephone health coaching sessions, each lasting 30-40 minutes.	Not applicable.
Monthly Surveys, approximately 10 minutes	Complete one survey per month (text message or online) asking you about health behaviors.	Complete one survey per month (text message or online) asking you about health behaviors.
3, 6, 9, and 12 month surveys, approximately 30 minutes	Complete questionnaires online or by telephone.	Complete questionnaires online or by telephone.
Urine Screening	You will be asked to provide a urine sample at the baseline visit, and at 6 and 12 months. Your provider will not see the results of the tests.	You will be asked to provide a urine sample at the baseline visit, and at 6 and 12 months. Your provider will not see the results of the tests.

After you have provided your consent, study staff will ask for a list of ways to contact you, such as your e-mail address and phone number, as well as the contact information for relatives or friends who know how to reach you. Study staff will not leave voice messages or text messages unless you give permission. The study staff will also not tell your relatives or friends anything about this study, your participation in the study, or any other information unless you give permission. Your contact information will be used to remind you about upcoming study surveys and telephone health coaching sessions. The follow-up surveys are very important to the study, and the research team will make every effort to contact you to remind you about these surveys. If research staff has difficulty getting in touch with you for your follow-up surveys, they may search public databases in an effort to try and locate you.

Urine Screening: Any urine specimen collected and/or used for the purposes of this research will not be used or distributed for future research studies. To ensure participants are able to provide the sample in the most convenient manner, sites have the option of collecting samples in the following ways:

1) In the clinic conducted by nurses or research staff.
2) At home, conducted by you and mailed back to the clinic for analysis.

Samples will be collected at the baseline visit, and at approximately 6 months and 12 months. The results of this urine test will be used for research purposes only. It will not affect your eligibility for this study and will not be shared with any clinical providers or staff.

Health and administrative records: Additional information on your health-related behaviors will be recorded from your medical records by the research team. We will review your medical records for the period of 12 months before your enrollment in the study and for the 12 month period during the study, for a total review period of 24 months. We will review your medical records to find information about the care that your primary care provider delivered, as well as your prior and current health conditions, medications, and use of health services.

Audio recording: For subjects participating in telephone health coaching**,** we would like to digitally audio record the counseling sessions. The purpose of this is to confirm that the health coaches are conducting the sessions in accordance with study policies and procedures. If calls are conducted via video chat, only audio (and not video) will be recorded.

If you agree to participate in this study, your initials below give the researchers permission to make and retain the audio recordings for this study. You have the right to review the recordings and to request that all or any portion of the recording be erased.

- Recordings will be accessed only by members of the research team who are trained and assigned to review recordings. This may include experts located at other research facilities also involved in this research.
- Recordings will be identified by a number to protect your identity and to ensure that your study information remains confidential. Recordings are labeled with a participant study ID number, session number and session date. Randomly selected session recordings will be reviewed for quality monitoring.
- Your name will not be recorded. Your name will only be linked to your study ID number in a secure and locked file cabinet and/or on password-protected computer. If you wish to not reveal who you are on the recording, do not say your name during sessions.
- At any time, you may choose to stop being recorded. If you choose to not be recorded, you can still be in this study, and your care will not be affected in any way. Recordings of an ongoing session can be destroyed, but once a recording has been submitted for quality monitoring it cannot be recalled.
- All study recordings will be kept in locked file cabinets and/or on password-protected computers. Only study staff will have access to them. All recordings will be destroyed after completion of the study.

I **agree** to have coaching sessions audio-recorded. _____
Initial here

I **decline** to have coaching sessions audio-recorded. _____
Initial here

RISKS AND DISCOMFORTS

Risks associated with participation are minimal. It is not anticipated that there will be any injury or adverse reactions caused by the study intervention.

Discomfort: You may feel uncomfortable or embarrassed by providing information about your health behavior, quality of life, or other information while answering surveys or speaking with research staff. You are free to provide as little or as much information as you like during the study. If any of the survey topics make you uncomfortable or if you find something upsetting, you can stop at any time.

You may stop participation at any time, without any consequences towards your care at the clinic.

Violation of privacy: Some personal and sensitive information will be requested from you during the course of this research study. There is some potential risk of disclosure of your personal information. The study team will ensure to the best of their ability that your information is kept safe, by storing all data and records on password-protected computers and/or in locked cabinets that are only accessible by research staff.

NEW INFORMATION

During the course of this study, we may learn more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

BENEFITS

As a result of your participation in this study you could potentially benefit, but there is no guarantee. Others may benefit in the future from what we learn in this study.

ALTERNATIVES TO STUDY PARTICIPATION

Your decision to participate is voluntary (of your own free will). If you decide to participate, you are still free to withdraw at any time without giving a reason, and without penalty or loss of benefits to which you are otherwise entitled. Should you choose not to participate, your medical care at [NAME OF SITE] will not be affected. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

COSTS OF PARTICIPATION

You will not have to pay for anything that is done in this study. If you are in need of medical care while enrolled in the study, you or your health insurance company will be responsible for paying any fees.

COMPENSATIONFOR PARTICIPATION

You will receive compensation payments via [INSERT FORM OF PAYMENT] for your time and assistance in the study [INSERT WHEN PAYMENT WILL BE GIVEN]. The table below details the payment for each study activity:

Study Activity	Compensation
Baseline Visit	$30 after completing surveys with research staff; and another $50 after completing additional self-administered baseline surveys (total $80)
Follow–up Surveys (3, 6, 9, and 12 months)	$50 each, totaling $200 for all four surveys
Urine Screenings (6 and 12 months)	$25 each sample, totaling $50 for both samples
Monthly Surveys via email/text message	$25 each month, totaling $300 for 12 months of surveys

Participants who complete consecutive monthly surveys will receive a $10 bonus payment (available in months 2, 3, 4, 5, and 6), for a maximum of $50 in total possible bonus payments.

If you complete all study activities listed above, the maximum amount you may be compensated is $680.

Group A participants who take part in telephone health coaching sessions will receive a payment of $3 per session to offset any costs they may incur from the telephone and/or video call (total of $6 for the first two sessions, and total of $12 more for those receiving four additional sessions).
Additionally, should your contact information change between study visits, you will receive a $5 incentive if you contact the research team and provide the updated information. Participants will be able to receive payment for updating their contact information up to four times, but are encouraged to inform study staff any time it changes over the course of the study.

If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed activity prior to withdrawal.

If you become a prisoner (including being in jail or prison, being on probation or parole, or being under house arrest or electronic monitoring), you will still be able to receive compensation for your continued participation in the study, if possible.

Tax law may require the payer (e.g. INSERT NAME OF SITE) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. You would be responsible for paying the taxes on the payment you received from the study. Generally, this reporting would take place if you receive $600 or more from [INSERT NAME OF SITE] in a calendar year.

COMPENSATION FOR INJURY

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the Site Principal Investigator as soon as possible. The Site Principal Investigator's name and phone number are listed at the top of page 1 of this consent form.

No injury-related compensation will be offered by the sponsor or [Insert name of Institution] or the Biomedical Research Alliance of New York. You do not give up your legal rights by signing this form.

INFORMATION ABOUT INCARCERATION

If you become a prisoner (including being in jail or prison, being on probation or parole, or being under house arrest or electronic monitoring), we would still like to find out how you are doing and if you completed the study questionnaires. If necessary, we will make an effort to collect follow-up data from you over the phone or in person. Please note that your continued participation in the study will have no effect on your criminal case, or release or parole from jail or prison, or probation case. In addition, knowledge of your participation in this research study will not be shared with prison staff, parole officers or probation officers, in any manner, to affect your conditions at the institution where you are held. Details of the nature of the research will not be shared with staff at the jail or prison, and visits, whether in person or by phone, and will only take place if your confidentiality can be maintained and no audiotaping occurs. If you do stop participating in this study, your sentence, probation or parole will not be affected in any manner.

<u>CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION</u>

To the extent allowed by law, every effort will be made to keep your personal and medical information confidential. You will be assigned a unique study ID number, and your name will not appear on the questionnaires that you submit for this study. However, total confidentiality cannot be guaranteed.

The study staff will use your medical information collected or created as part of the study, such as medical records, test results and research records. Some of this information may identify you by name or in another way. The following information may be used or shared with others in connection with this study:

- Your name, demographic information, and contact information
- Your responses to interviews and surveys, including responses collected during the prescreening and screening phases of this study that you provided before giving consent to join the study.
- Information from your medical record about the care you received from your medical providers, prior and current health conditions, medications, and use of health services

The study staff may use and share information about you and your health with other professionals involved in the study, including the Biomedical Research Alliance of New York, New York University School of Medicine's Institutional Review Board, the members and staff of [INSERT NAME OF SITE'S] Institutional Review Board, [NAME OF SITE PI] and members of the research team who are responsible for the support or oversight of the study, the following research sponsors and the people and companies they use to oversee, administer, or conduct the research: The National Institutes of Health, and New York University School of Medicine researchers who are the lead site for this study, United States research regulatory agencies, the Patient Advocate or Research Ombudsman, Members of the [NAME OF UNIVERSITY AND/OR SITE] Clinical Trials Office/Office of Research and Sponsored Programs (if applicable), Clinical Coordinating Center (Contract Research Organization): Emmes, Data and Statistics Center (Contract Research Organization): Emmes, and the Data Safety Monitoring Board / Clinical Events Committee.

Additionally, if you are in Group A, your primary care provider, nurse care manager, and telephone health coach will receive the results of your first Healthy Living Survey. They are all members of your health care team, and they may discuss among themselves ways of coordinating care to better assist you. However, they will not receive results of any other surveys, interviews, or urine tests that are collected for the study.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to re-disclosure by the recipient. The purposes for using and sharing your medical information include: to carry out the research study and evaluate its results and to meet government reporting requirements. Results of this research may be presented at meetings or in publications. Your name will not be used in any study reports or presentations. You have the right to review and copy your health information, but you may not be allowed to do so until after the research is completed.

This authorization does not have an expiration date. You have the right to cancel your consent at any time by giving written notice to [NAME OF SITE PI] at [ADDRESS OF SITE PI]. If you withdraw your permission, you will not be able to continue in this study, but you will not lose access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information about you will be gathered after that date. Information that has already been collected may still be used and given to others.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. You will be able to find a listing for this study by searching for NCT04218201, which is the specific identifier for this study.

De-identified data (which cannot be used to identify you) from this study will be available to researchers on another website, https://datashare.nida.nih.gov/ after the study is complete and the data analyzed. The primary outcome(s) publication for the full study will also be included along with study underlying primary data in the data share repository, and it will also be deposited in PubMed Central http://www.pubmedcentral.nih.gov/. These websites will not include information that can identify you. You can view these websites at any time.

After identifiers are removed from your information (making it anonymous), the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. However, any urine specimens collected and/or used for the purposes of this research will not be used or distributed for future research studies.

Certificate of Confidentiality:
To help us further protect your confidentiality, the National Institutes of Health (NIH) has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data or documents) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or

local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse). The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment.
You should also understand that even with a Certificate of Confidentiality, if we learn about abuse of a child or elderly person, or that you intend to harm someone else, the investigators have certain obligations to report that information to the proper authorities or parties in order to reduce the chances that serious harm will occur to either you or others. Should we learn that you intend to harm yourself, the investigators may be obligated to disclose your intent to other providers in order to reduce the chances that serious harm will come to you. Federal regulations may also allow for the use or sharing of information for other scientific research.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation in this study is voluntary. The study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation may be terminated at any time by your physician, the study investigator, or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study, has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your standing as a patient of this clinic. If you do decide to withdraw your consent, we ask that you contact [NAME OF SITE PI] and let him/her know that you are withdrawing from the study. His/her mailing address is [ADDRESS OF SITE PI].

Permission to Contact You about Future Research

In the future, if there are additional research studies that we think you may be eligible for, can we contact you regarding these other study opportunities? Please note that participation in any additional study is entirely voluntary and refusing to volunteer for an additional study will not affect your participation in the study.

I **agree** to be contacted for future research studies. _____
Initial here

I **decline** to be contacted for future research studies. _____
Initial here

QUESTIONS/COMPLAINTS/CONCERNS

If you have any questions relating to this research study or your participation in it, if you want to voice a complaint or concern about this research, or if you experience a research-related injury, you may contact [INSERT NAME OF SITE PI] at [INSERT SITE PI PHONE NUMBER].

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board (BRANY) at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT

I have read this consent form. I have been informed of the risks, discomforts, and benefits involved. All of my questions have been answered to my satisfaction. The study staff will answer any future questions I may have. I will be given a copy of this signed consent form.

By signing this consent form I voluntarily agree to participate in this study, and agree to provide my Authorization for the uses and disclosures of my protected health information as described above.

_____
Participant's Name
(Printed)

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Consent and Authorization
(Printed)

_____ _____
Signature of Person Obtaining Consent and Authorization Date

[INSERT ADDITIONAL SIGNATURE LINES IF LOCAL PARTICIPATING SITE REQUIRES]