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| **Official Title:** | Behavioral Economics Trial To Enhance Regulation of Blood Pressure (BETTER-BP) |
| **NCT Number**: | NCT04114669 |
| **Study Number:** | s19-00952 |
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NYU Langone MEDICAL CENTER

# Research Subject Informed Consent Form

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| **Title of Study:** | Behavioral Economics Trial To Enhance Regulation of Blood Pressure (BETTER-BP)<br>s19-00952 |
| **Principal Investigator:** | John Dodson, MD, MPH, FACC<br>Leon H. Charney Division of Cardiology<br>NYU School of Medicine<br>227 E. 30th Street, Translational Research Building,851<br>(646) 501-2714 |
| **Emergency Contact:** | John Dodson, MD, MPH, FACC<br>(646) 501-2714 |

## 1. About volunteering for this research study

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.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

## 2. What is the purpose of this study?

The goal of this research study is to understand whether a lottery program implemented for 6 months can improve medication adherence, and consequently, systolic blood pressure among participants who are diagnosed with hypertension (high blood pressure). The researchers would also like to evaluate whether there are patterns of adherence among participants who receive the lottery program.

You have been asked to take part in this study because you are 18 years of age or older, have a diagnosis of hypertension, are prescribed with 1 or more antihypertensive medication, and have reported to be less adherent with your antihypertensive medication(s). Participation in this study will in no way affect your standard of care at NYULMC or NYULMC-affiliated hospitals, as determined clinically appropriate by your doctor and healthcare team.

## 3. How long will I be in the study? How many other people will be in the study?

This study will last about 12 months and will involve about 3 visits.

About 525 study participants will be consented and 435 study subjects are to be randomized into this study across all sites.

## 4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before any study procedures happen.

This study is randomized, meaning if you are eligible to be in the study, you will be assigned by chance, like flipping a coin, to either the Control (Usual Care Group) or Intervention Group. There are no special requirements or criteria to be in either group. You will have a 2 out of 3 (67%) chance of receiving a lottery software application and monitoring medication-taking activities, and a 1 out of 3 (33%) chance of receiving standard medical care and monitoring of medication-taking activities.

### a. Baseline Visit (Intervention Group and Usual Care Group)

After signing the consent form, the research coordinator will spend about 60-75 minutes with you. At this visit the research coordinator will:

- Interview you to collect general information such as contact information and demographics (age, race, gender, education, etc.), and information about your health, symptoms, medication adherence, and lifestyle.

- Conduct a brief physical assessment, which will include the following:
  - Measurement of height and weight
  - Measurement of blood pressure and pulse rate

- Conduct questionnaires about your health, symptoms, medication adherence, lifestyle, and health goals.

- Provide you with an electronic monitoring device to monitor and collect medication-taking activity. **This information will not be used as part of your clinical care. If at any point you believe that you are experiencing symptoms related to your heart, please call 911.** You will be using an electronic monitoring device that will function as your regular medication bottle throughout the study period. A single antihypertensive medication will be selected by the research coordinator to be placed in this device. In the event that you do not have your medications with you, the research coordinator will follow-up by phone to instruct you on how to place the antihypertensive medication into the electronic monitoring device. **NOTE: The bottle is designed to glow blue to remind you to take your medicine, but this feature has been disabled. The bottle will not provide you with a reminder when it is time to take your medicine.**

- Provide you with instructions on how to refill your medication into the electronic monitoring device throughout the duration of your involvement in the study.

**One Week Call**:
One week after your baseline visit, the research coordinator will call you on the phone to ask if you have any questions about the smart pill bottle and to provide you with help using the bottle if you need it.

**b. Intervention (Intervention Group Only)**

- You will receive Short Message Service (SMS) text messages delivered via Way to Health platform for the duration of 6 months. You are not required to install a separate software application. If you do not have a smartphone, the study team will work with you on providing you with one for the study duration. Way to Health will inform you daily whether you qualify for the lottery, depending on your adherence to taking your antihypertensive medication as monitored by the electronic monitoring device. You will be asked to check text messages from the daily lottery draw, daily.

  Information regarding your medication-taking activity will be recorded. This information will include measures such as number of times the bottle cap has been opened, and the number of times you have been, or would have been, eligible for the lottery. **Your medication-taking activity data will not be monitored in real time and therefore this information will not be used as part of your clinical care. If at any point you believe that you are experiencing symptoms related to your heart, please call 911.**

- You will receive a detailed explanation by the research coordinator on the purpose of the lottery, how to qualify, how to cash out the rewards, and answer other questions you may have about the lottery program. The lottery is a component of the Way to Health platform. The lottery will automatically enter you into the draw daily if you are adherent with your medications, as monitored by the electronic monitoring device. The research coordinator will explain to you on how to keep your devices prepared and synced in order to be entered into the lottery draw daily.

  You are eligible to receive a potential cash reward if you are adherent with their antihypertensive medication the day before, which is monitored through the electronic monitoring device. You will be assigned a 2-digit number for the trial, and each day the Way to Health platform randomly generates a 2-digit number. You will receive $50 if both digits match (1 in 100 chance) and will receive $5 if one digit matches (18 in 100 chance). If you are not adherent with your medication, you will not be entered in the daily lottery draw.

**c. Follow-Up Visit 6-months after baseline visit (Intervention Group and Usual Care Group)**

The Research Coordinator or other member of the study team will schedule you for a visit at six months after baseline visit to perform a follow-up assessment, that will include many of the questions and physical assessments from your initial baseline visit. This visit will occur at the NYU main campus. The research coordinator will spend around 30-45 minutes with you. The questions will be regarding your health, symptoms, lifestyle, and any possible readmissions to the hospital since your first baseline visit.

The research coordinator will also assess and verify your blood pressure and laboratory values from your ambulatory visits through your medical chart.

The research coordinator will then conduct a second brief physical assessment, which will include the measurement of blood pressure and pulse rate.

**One Week Call after 6-month visit**:
One week after your 6-month visit, the research coordinator will call you on the phone to ask if you have any questions about the smart pill bottle and to provide you with help using the bottle if you need it.

**d. Follow-Up Visit 12-months after baseline visit (Intervention Group and Usual Care Group)**

The Research Coordinator or other member of the study team will schedule you for a visit at 12 months after baseline visit to perform a follow-up assessment, that will include many of the questions and physical assessments from your six-month follow-up visit. Similar to the 6-month visit, this visit will occur at the NYU main campus and the research coordinator will spend around 30-45 minutes with you. The questions will be regarding your health, symptoms, lifestyle, and any possible readmissions to the hospital since your second visit. The research coordinator will also assess and verify your blood pressure and laboratory values from your ambulatory visits through your medical chart.

The research coordinator will then conduct a third brief physical assessment, which will include the measurement of blood pressure and pulse rate.
During this visit, the Research Coordinator or other member of the study team will then collect the electronic monitoring device, and if applicable, the smartphone provided to you by the study team during baseline visit. The Research Coordinator will also assist and/or provide instructions on how to remove the Way to Health software from your personal mobile device.

**e. Review of Hospital Medical Records**

We will review your medical record for your initial hospital visit and for any other hospitalizations that occur over the next 12 months. We will use this information to understand your medical history, diagnosis, and the details of possible readmissions.

## 5. What are the possible risks or discomforts?

There is a small possibility that your information could be viewed by someone who is not authorized to do so. All electronic records are accessible only to the New York University Langone Health (NYULH) research staff who undergo thorough training in data management and security. Any data collected on paper copy will be stored in a locked cabinet on a secure floor that requires an NYULH ID for entry. Any relevant medical records will only be viewed by authorized research staff. Data input from the applications on the smartphone and the electronic monitoring devices will be transferred to the NYU study team and stored in a secure HIPAA-compliant internet-based platform that is only accessible by authorized research staff. Data obtained through the applications will be given a random study number that is de-identified from all personal identification indicators, therefore ensuring patient confidentiality from thedevices.

There is a small chance that improved adherence related to the study intervention may have the consequence of medication-related adverse effects. We will therefore capture any event that is, or might be, a result of the intervention, including any of the following: (1) fall-related injury; (2) syncope (loss of consciousness); (3) hypotension (low blood pressure); (4) bradycardia (slow heart rate); (5) renal or electrolyte (kidney or salt) abnormality. Due to the absence of these data reported in previous studies, we anticipate that adverse events specifically related to hypotension from better adherence with a single medication (e.g. fall-related injury, syncope, hypotension) are unlikely.

## 6. What if new information becomes available?

During the course of this study we may find 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.

## 7. What are the possible benefits of the study?

There is no definitive direct benefit to participants from study treatment or other study procedures during the course of the study. If the adherence intervention turns out to be beneficial, then participants assigned to this study arm will benefit, although this will not be known until conclusion of the study. We hope the information from this study will help future patients with your condition.

## 8. What other choices do I have if I do not participate?

Declining to participate in the present research study will in no way affect your standard care for your hospitalization or heart disease. Other alternatives aside from participating in this study can be further discussed with your personal physician.

## 9. Will I be paid for being in this study?

You will be paid per completed visit. After you are enrolled and complete the baseline interview and assessments, the research coordinator will give you a $50 compensation loaded to the ClinCard. After you complete a 6-month follow-up visit, the research coordinator will reload $50 to the ClinCard; and after you complete a 12-month follow-up visit, the research coordinator will reload $50 to the ClinCard. This compensation is inclusive of travel costs.

If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed visit. If you complete all the study visits, you will receive the indicated total of $150 for being in this study.

In order for you to receive a payment card, you may need to give the study staff either your Social Security number or your Alien Registration number. If you do not have either of these numbers, you may be in the study but will not receive any payment.

## 10. Will I have to pay for anything?

There are no anticipated costs to you for participating in the research study. If you are assigned to the intervention group, there will be no costs associated with these procedures.

The electronic monitoring device, and if applicable, the smartphone device, will be provided to participants at no cost, but must be returned to the study team at the end of the study.

## 11. What happens if I am injured from being in the study?

**For medical emergencies contact 911.**

If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

## 12. When is the study over? Can I leave the Study before it ends?

This 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 ended at any time by your physician or the 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 future care, payment for your health care or your eligibility for health care benefits.

## 13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

**Certificate of Confidentiality**

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) 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 or communicable diseases).

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. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing **t**o be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

## 14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

**What information may be used or shared with others in connection with this study?**
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this study?**
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institutes of Health/National Heart, Lung, and BloodInstitute
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at Bellevue

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**How long may my information be used or shared?**
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

## 15. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. _____ Subject Initials

☐ Checking this box indicates my permission to be contacted by this study team after my completion of the study about taking part in future research.

_____
Subject Initials

## 16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

## 17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

| Name of Subject (Print) | Signature of Subject | Date |
|---|---|---|

| Name of Person ObtainingConsent (Print) | Signature of PersonObtaining Consent | Date |
|---|---|---|

**Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language**

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

| Name of Witness (Print) | Signature of Witness | Date |
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