ADULT CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study
The Rural Men's Health Study

Invitation
You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are a 40 to 69 year old man, reside in the Northeast Nebraska region, your Body Mass Index (BMI) is 28 or higher (BMI 50 or greater with clinician clearance, less than 396 pounds), you are a smartphone owner with enabled text messaging, you speak and read English, have an email account, you have no health problems that would prevent you from becoming more physically active, and you are willing to share your self-monitoring logs from the Lose-It app with the investigative team.

What is the reason for doing this research study?
Rural men are less likely than the general population to receive diet and exercise counseling for weight loss. Men with BMI of 28 to 49 are classified as overweight or obese BMI of 50 or higher is classified as morbidly obese. This population is at increased risk of developing a number of chronic diseases such as insulin resistance, Type 2 (adult-onset) diabetes, high blood pressure, heart disease, and cancer. The preferred treatment for weight reduction is lifestyle modifications that include a diet that is high in fruits, vegetables and low fat dairy products, and regular moderate intensity physical activity supplemented by resistance exercise. This research is trying to see if a technology enhanced self-monitoring approach is effective in increasing healthy eating and physical activity and reducing body weight. A total of 80 participants are expected to enroll in this study.

What will be done during this research study?
The study will last for six months. You will be asked to come to meet with a research nurse for an independent meeting at the Northeast Nebraska Public Health Department in Wayne, NE, three times at regular intervals (baseline, 3, 6 months) to complete surveys and physical assessments, which will take approximately 60-90 minutes. The physical assessments will include weight, height, body mass index, blood pressure, and heart rate. The individual contents of your written survey will only be shared with the research team. The surveys will include questions about your

health status, your eating and physical activity patterns, and your perceptions about technology.

Immediately after the baseline visit, you will be randomly assigned (as by the roll of a die) in a 1:1 ratio to one of two groups. All subjects will be assigned a temporary email address, that contains no personal identifiers, that will be used to create a Lose-It app account. At the end of the study, you will have the option to choose to obtain personal ownership of your Lose-It account. If you choose to obtain personal ownership of your account, our research staff will assist you in entering a new username and password. However, please be advised that our study will not pay for further access to the Lose-It app. Future access to Lose-It premium will require you pay the current market rate for the app. If you choose to forego a change of ownership, your Lose-It account will be deleted 30 days after completing the study. If you are in group 1, you will have access to Lose-It Premium app, receive daily text messaging, participate in an online social comparison group with other members of group 1, and receive a WiFi Smartscale for daily weighing over the next 6 months. If you are in Group 2, you will have access to the Lose-It Basic app to self-monitor your eating and activity for the next 6 months. Both groups will have access to the research nurse for questions and will receive assessments at 3 and 6 months.

An overview of the procedures you will participate in during the study office visits are outlined in the attached table: Schedule of Procedures.

In addition to the brief questionnaires collected at baseline, 3, and 6 months, you may be randomly invited to participate in a face-to-face focus group interview (approximately 90 minutes) at the end of the study (6 months) at the same community center where your assessments were collected. The questions for the interviews and focus groups will be: 1) What was the most helpful aspect of this study? 2) What other support would have helped you reach your goals? 3) Other comments. The interviews and focus groups will be recorded and analyzed to determine the major themes. Audio recordings of the focus groups will be destroyed after checked against the written transcripts for accuracy. At the end of the study, your temporary email account and attached Lose-It account will be deleted. You will have the option to set up a new Lose-It Basic account for free if you choose to continue using the app after the completion of the study.

What are the possible risks of being in this research study?

The possible risks of the procedures for assessing the biomarkers (resting blood pressure and resting heart rate) can be compared to procedures used in routine medical care and/or screens (i.e., blood pressure or heart rate measurement).

Assessment of Behavioral Markers:The assessments include no sensitive questions and pose no risks to you beyond possible but unlikely fatigue during completion of the survey. If you become fatigued, you can take a break or complete the assessment on another day.

Assessment of Biomarkers:The likelihood of risks associated with the assessment of all biomarkers is small, and the seriousness of those risks in minimal. The exertion levels are the same as for those associated with routine clinician visit screenings.

Alternative Treatments and Procedures:You can obtain guidance from your primary care provider or follow self-directed programs of behavior change. The assessments provided might be available from health clubs or other facilities, but there would be a cost associated.

Use of smart phone to track physical activity:The risks associated with wearing your smart phone for tracking physical activity are minor discomfort and nuisance from wearing the device on the hip or pocket during waking hours.

Loss of confidentiality is a risk to participating in the study. You may find completing the written surveys and health assessments inconvenient or tiring. The research nurse will schedule all assessment sessions at times convenient for you, and you may call him/her at the number listed at the end of this form to reschedule if necessary. If you become tired before completing the surveys or health assessments, you may take a break. Lose-It Corporation, the owner of the Lose-It app, will not have access to any personal identifiable information about you or any other subjects in the study.

You may experience the following risks and discomforts as a result of each part of the physical assessment:

Resting Blood Pressure: arm discomfort during the procedure related to compression by the blood pressure cuff.

All of the tests will be administered by an experienced licensed or certified healthcare professional who will provide you with instruction and support during testing.

It is possible that other rare side effects could occur that are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits to you?
You may learn about weight loss through self-monitoring of healthy eating and physical activity. If you adopt healthier eating and physical activity lifestyle behaviors, you may experience weight loss as well as promote health, prevent disability and/or premature death, and enhance quality of life as you age. You also may benefit from an improvement in cardiorespiratory (heart) fitness, increases in muscular strength, and percent body fat. You may not get any benefit from being in this research study.

What are the possible benefits to other people?
Cost-effective interventions that are acceptable to rural men and effective in achieving preventive health behavior change have the potential for decreasing health care costs by preventing chronic diseases and maintaining functional ability. This research protocol may provide a care delivery model that can be used by other providers of primary preventive services to rural clients. There may not be benefits to other people.

What are the alternatives to being in this research study?
You might obtain guidance from your primary health care provider about healthy eating and physical activity or follow a self-directed program of lifestyle behavior change for weight loss. The assessments provided might be available to you at health clubs or other facilities, but there would be a cost involved.

What will being in this research study cost you?
There is no cost to you to be in this research study. You will not be paid or reimbursed for transportation costs to and from the study site.

Will you be paid for being in this research study?
You will not be paid for transportation costs to and from the study site. Your compensation will be determined by the intervention arm to which you are randomly selected. Men in the MT+ intervention arm will receive the Lose-It Premium app (40.00) and a Nokia Body+ Wi-Fi scale (100.00), which they will be able to keep at the end of the study. Men randomized to the MT intervention arm will receive a stipend of $25 for each of the 3 assessment sessions. To receive payment you must provide your social security number, name, and address in order to comply with Internal Revenue service (IRS) reporting requirements. When payment is reported to the IRS, we will not say what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still participate in the study; however, you will not be paid. Checks will be mailed at the end of 6 months of your participation after your final study visit.

Who is paying for this research?
This research is being paid for by grant funds from the National Institute for Nursing Research. The University of Nebraska Medical Center College of Nursing receives money from the National Institute for Nursing Research to conduct this study.

What should you do if you are injured or have a medical problem during this research study?
If you are injured or have a medical problem as a result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called "protected health information" (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, as well as your medical history.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC. Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

Who will have access to information about you?
Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your PHI with other people or groups listed below. All of these persons or groups listed below are obligated to protect your PHI.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?
The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

A description of this clinical trial will be available on 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.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research study will not affect your medical care or your relationship with the investigator, the University of Nebraska Medical Center or the Nebraska Medical Center. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research study (withdraw) at any time before, during, or after the treatment begins. Your doctor will still take care of you though you may not be able to get the research treatment. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator, the University of Nebraska Medical Center, or the Nebraska Medical Center. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "What do I need to know before being in a research study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in *The Rights of Research Subjects* that you have been given. If you have any questions concerning your rights or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB) by
- Telephone: (402) 559-6463
- Email: IRBORA@unmc.edu
- Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830.
- Research subject advocate
- Telephone 402-559-6941

- Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____
Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel

Principal

* Eisenhauer, Christine
phone: 402-844-7897
alt #: 402-844-7897
degree: PhD, APRN-CNS

Secondary

* Hageman, Patricia
phone: 402-559-1967
alt #: 402-559-1967
degree: PhD, PT

* Pullen, Carol
phone: 402-502-1444
alt #: 402-559-6548
degree: Ed.D., RN

* Silva, Fabiana

* Yoder, Aaron

phone: 402-559-6627
alt #: 402-559-6627
degree: PhD

phone: 402-552-7240
alt #: 814-577-9127
degree: PhD

Participating Personnel

* Castaneda, Georgina
alt #: 402-375-2200
degree: CHW

* Miller, Jessica
alt #: 402-340-4699
degree: RN, BSN

* Salinas, Katherine (Katie)
phone: 405-255-0504
alt #: 402-255-0504
degree: RN, BSN

* Zarate, Victor
alt #: 402-375-2200
degree: CHW

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasnˆt in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once Iˆve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ˆ

ˆ to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

ˆ to freely decide whether or not to take part in the research.

ˆ to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

ˆ to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

ˆ to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

ˆ to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

ˆ to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.