Informed Consent Example for Study Teams

**UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT & HIPAA AUTHORIZATION FORM**

Protocol Title:  A Randomized Controlled Trial of XYZ

Principal Investigator:  John Smith, MD, PhD

Contact: University of Pennsylvania

123 Penn Way

Philadelphia, PA 19104

Phone: 215-123-4567

smith@example.com

Emergency: In the event of an emergency, please contact your primary care physician or go to the nearest emergency room.

**Why am I being asked to volunteer?**

The University of Pennsylvania is partnering with XXXX.  Your participation in this study is voluntary, which means you can choose whether or not you want to participate. In order to assist you in making an informed 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 be asked to do in this study. The following screens will explain the study in detail. After reviewing this information, you will have the option to participate in the study or to not participate. If you choose to participate in this study, you may withdraw at any time.

**What is the purpose of this research study?**

The purpose of the study is to learn more about XXXX. We will test different strategies for helping people XXXX.

**How long will I be in the study?**

How many people will be in the study? The study will last for 24 months. A total of XX adults will participate in the study. The participants will be employees at XXXX.

**What am I being asked to do?**

1. During the enrollment process, you will be asked to complete an online questionnaire. You do not have to answer any questions that make you feel uncomfortable. The online survey should take about 10 minutes to complete.

2. If you meet the necessary requirements for the study, you will be "randomized" into one of 4 research study groups. Randomization means that you are put into a group by chance. A computer program will place you in one of the research groups. Neither you nor the researchers can choose the group you will be randomly placed in..

**What are the possible risks or discomforts?**

The risks of participation are expected to be minimal. All study participants will be screened through eligibility requirements for any health conditions that might worsen by participating in a XXXX study. You may not be in this study if you are pregnant or if you become pregnant during the study. There is a minor risk of loss of confidentiality and privacy. The research team will take the necessary precautions to make sure your privacy is maintained.

**What if new information becomes available about the study?**

During the course of this study, we may find out information that could be important to you. We will notify you as soon as possible if such information becomes available. You will always have the right to change your mind about being in this study. What are the possible benefits of the study?       Participation in this study may help you XXXX. There may be many benefits of XXXX; may result in improvements with high blood pressure, diabetes, high cholesterol, arthritis, sleep apnea, and many other obesity-associated conditions. In addition, the knowledge we gain from the study will assist in helping others.

**What other choices do I have if I do not participate?**

Your alternative to being in the study is to not be in the study. If you choose not to be in the study you may always consult with your primary care doctor.

**Will I be paid for being in this study?**

Everyone in this study will have the opportunity to earn a total of $XXXX.  In addition, some participants may earn additional money.

In order to be paid for participating in this study, you will be asked to provide your Social Security number. The University of Pennsylvania requires that we collect Social Security numbers for all research participants who get paid for being in a research study. You do not have to provide your Social Security number, but if you choose not to, you will not get paid for your participation.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual is $600 or more in any one calendar year, the University of Pennsylvania is required to report this information to the Internal Revenue Service (IRS). Research participant payments of $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

**Will I have to pay for anything?**

If you choose to receive communication messages from the Way to Health study website in the form of a text message, you will be responsible for the costs associated with the receipt of these text messages. For example, if you have a monthly text-messaging plan, these messages will count towards your monthly text-messaging total. If you do not have a plan, you will be charged the standard text messaging fees by your wireless provider. You may receive a maximum of 35 text messages from the Way to Health study website each month. You can edit your Way to Health profile or contact the study research team at any point during the study to change your communication preferences.

**When is the study over? Can I leave the Study before it ends?**

The study will last for XXXX months/years following the date you enroll. If you decide to participate, you are free to leave the study at anytime. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care. If you no longer wish to be in the research study, please contact the Project Manager.

Your participation in the study may be terminated without your consent for the following reasons:

* The Principal Investigator (PI) feels it is best for your safety and/or health. If this is the reason for termination you will be informed of the reasons why.
* You have not followed the study instructions.
* The PI, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

**Use of Study Materials**

Information about you that is collected during the study will not be given to others (unless it is required by a government agency or other legal authority). This means that no one (not your family, your doctor, your insurance company, or your employer) will have access to this information during the study.

**Who can see or use my information? How will my personal information be protected?** The Principal Investigators and research staff involved with the study will keep your personal information strictly confidential. It will be kept in a secured, password-protected file at the University of Pennsylvania. At any time, you may ask to see your personal information (such as name and address) and correct it if necessary.

**What information about me may be collected or shared with others?**

* If you decide to participate we will collect the following information:
* Name, mailing address, electronic mail address, telephone number, and social security number Height, weight, glucose, cholesterol, blood pressure
* Personal characteristics such as age, gender, race, income, education, health
* Questionnaire data about dietary and exercise habits
* Cardiovascular risk factors, including: diabetes, high cholesterol, smoking status, high blood pressure (if applicable)
* Medical benefit claims information from your insurer, which is relevant to our research. (This statement applies only to enrolled participants who are insured by XXXX.
* Biometric screening results from your employer, or your employer’s health management vendor. Information on the use of wellness program activities provided by your employer (if applicable to you).

This information will be collected from the time you enroll in the study, until your completion date of the study.

* The medical benefit claims information, use of wellness program activities, and biometric screening results will only be collected from the time you enroll in the study until your completion date of the study.

This personal information will not be shared with your healthcare providers, your insurance company, or your employer. When you sign this consent form, you agree to have your personal and medical information obtained used as described here.

**Who, outside of the University of Pennsylvania, might receive my information?**

* Wells Fargo (We will share your Name and Address with Wells Fargo in order to coordinate your payments). You can review the privacy policy here: https://www.wellsfargo.com/privacy\_security/privacy/individuals
* Withings (to record your weight from the wireless scale. Withings may also ask you to provide your name and date of birth to create an account in order to set up the scale, if you receive one, but we will not be collecting this information). You can access privacy information on Withings website: http://www.withings.com/en/wirelessscale/faq:
* Twilio Cloud Communication (We will only provide your phone number to send you text messages, and you will only receive study related text messages). You can review the privacy policy here: http://www.twillio.com/legal/privacy
* Qualtrics (We won’t be sharing any of your information with Qualtrics.  We will only be interacting with Qualtrics to use their online survey service and to collect your answers to survey questions)

**Why is my information being collected, and how will it be used?**

Your personal information will be used by the research team to contact you during the study. Your responses to questionnaires and results of weigh-ins will be used to:

Do the research

Oversee the research

Make sure the research was done correctly

Ensure that payment for your participation in the research is sent to you

**How long may the University of Pennsylvania use or disclose my personal health information?**

Your authorization for use of your personal health information for this specific study does not expire. Your information will be held in the research database. However, the University of Pennsylvania may not re-use or disclose information collected in this study for a purpose other than this study unless: You have given written authorization The University of Pennsylvania Institutional Review Board grants permission As permitted by law

**Can I change my mind about giving permission for use of my information?**

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study PI (contact information on the first page). If you withdraw your permission, you will not be able to stay in this study.

**What if I decide not to give permission to obtain and use my personal health information?**

Then you will not be able to be in this research study. You will be given a copy of this Informed Consent and Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document you are permitting the University of Pennsylvania to use and disclose personal health information collected about you for research purposes as described above.

**Who can I call with questions, complaints 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 PI listed on Page 1 of this 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 Office of Regulatory Affairs at the University of Pennsylvania with any questions, concerns or complaints by calling (215) 123-4567.

**Next steps**

When you click the "I want to participate" button below, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Clicking the "I want to participate" button also means that you are permitting the University of Pennsylvania to obtain and use personal health information collected about you for research purposes within our institution.

Please select your choice and then click the NEXT button on the right to continue.

* I want to participate
* I do not want to participate