Informed Consent Example

**UNIVERSITY OF PENNSYLVANIA  
 COMBINED INFORMED CONSENT and HIPAA AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY**  
    
     This is a clinical trial led by Dr. XXXX XXXX at the University of Pennsylvania.  This physician and the study staff are available to answer any questions you may have.

Your participation in this study is voluntary, which means that you can choose whether or not to be in the study. Before you can make your decision, you will need to know the study’s purpose, your role in the study, and possible risks and benefits from participating. The following sections will explain the study in detail. After reviewing this information, you will see an option to select whether or not you would like to participate in the study. If you choose to participate and are enrolled, you may withdraw from the study at any time.

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

The purpose of the study is to learn more about ways to promote XXXXX.

**How long is the study?**

This study will take about XX months to complete.

**Am I eligible to participate in the study?**

To participate, you need to be 18 to 70 years old, have a body mass index of 25 or greater, have a smartphone or tablet (e.g. iPhone, iPad, Samsung, Google or Android) that is compatible with the wearable activity tracker used in the study, have no medical condition or other reason you could not complete the XX-month study.

If you are participating in another research study focusing on physical activity, you are not eligible to participate in this study.  You can participate if you a member of a program targeting these areas (e.g. exercise class, weight watchers) but not a research study. You must be willing to wear an activity tracker on your wrist during the day and night for approximately XX months. The device will be provided to you at no cost.

**What will happen if I take part in this research study?**

You will first complete a short questionnaire to determine if you are eligible to participate. If you are eligible to participate, you will be mailed a wearable activity tracker to use for about XX weeks. While you get used to wearing the watch, you will be asked to complete a series of online surveys in order to complete enrollment in the study. You will be randomly assigned to one of several physical activity programs.  You may be randomly assigned to participate by yourself or with other participants.

**How will I receive communications from the study?**

You can select whether you would like to receive communications from the study by email or text message.  Standard text messaging charges may apply. You may be contacted daily with feedback on your performance during the study. Additionally, you will be contacted if there is any other study activity that needs to be completed.  You may change your communication preference at any time during the study.

**Will I be paid for taking part in this study?**

Yes, you can receive a total of up to $XXX during the entire study. You will receive $XX to enroll in the study and another $XX for using the wearable activity tracker through X months and completing study surveys.  Additionally, you will receive another $XX for using the wearable activity tracker through one year and completing additional study surveys.

**What information will I need to provide to receive compensation and how is that information protected?**

To mail your financial payments, we will need to collect your name and address. Since all university payments must be reported to the Internal Revenue Service (IRS), we will also need to collect your social security number (SSN). Your information will be kept in a secured, password-protected file at the University of Pennsylvania.  Your information will be transmitted and stored using very secure systems.  The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential.  All of these personnel will have completed research and confidentiality training.

**Are there any costs to participate in this study?**

There is no cost for you to participate in the study. However, if you choose to receive study communications via text message, standard text message charges may apply.  You may select to have all communications sent by email instead.

**Can I stop participating in the study?**

Yes, this study is voluntary.  You can decide to stop participating at any time.  We won’t delete the information about you that we’ve already collected, but we will stop collecting any new information about you and will stop contacting you.  To stop participating in the study, please contact the study staff either by phone at 111-111-1111 or by email at example@waytohealth.org.  
     
**What side effects or risks can I expect from being in the study?**

This study does NOT involve the use of any medications that could lead to side effects.  If you have any health conditions that prevent you from being in a physical activity program, you should not participate in this study.  During the study, information about you and your activity will be recorded.  There is a risk of breach of confidentiality and privacy.  The research team will take precautions to make sure your privacy is maintained.  We will use commercial-grade encryption to protect your information similar to that which is used to protect electronic health records.  Your personal information will only be used by study team members who have been trained to use secure protocols to maintain the privacy of your data.  Whenever possible, data will be de-identified to protect your privacy.      
   
**Are there benefits to participating in the study?**   
By participating in this study, you will have the potential to increase physical activity, which could improve your health. If this study finds approaches that are effective, it could have benefits for society.  However, it is possible that you may receive no benefit from participating in this study.

**How is my information protected?**

We will do our best to make sure that the personal information we collect about you is kept private and secure. Your personal information will only be given out if necessary (e.g., if required by law to prevent possible injury to yourself or others).

Your information will be kept in a secured, password-protected file at the University of Pennsylvania. Your information will be transmitted and stored using very secure systems. The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential. All of these personnel will have completed research and confidentiality training.

Your SSN will only be shared with the US government if a W-9 form is submitted for tax purposes and will never be disclosed to any other partnering organizations. Please refer to information below that explains more specifically how your personal information will be used.

• Wells Fargo Bank (to coordinate your study payments)

• Twilio Cloud Communications (to send you text messages)

• Qualtrics (to collect your answers to survey questions)

• Quest (to collect your laboratory blood test measures)

• Nokia (to collect data on your physical activity, sleep patterns, and weight)

• The Office of Human Research Protections at the University of Pennsylvania

• Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.

Once your personal information is disclosed to others outside the University of Pennsylvania, it may no longer be covered by federal privacy protection regulations. You can review the privacy policies of these companies here:

• Wells Fargo: https://www.wellsfargo.com/privacy\_security/privacy/individuals

• Twilio Cloud Communications: http://www.twilio.com/legal/privacy

• Qualtrics: http://www.qualtrics.com/privacy-statement/

• Nokia: http://www.nokia.com/en\_int/privacy

**What other information about me may be collected, used or shared with others?**   
To create your account, we will collect your name, date of birth, and ask you questions about your background such as gender, education, and income level.  To contact you during the study, we will collect your email address and phone number.   
     
**Who may use and share information about me?**    
Your information may be used by authorized members of the UPenn study team.

**Who, outside of the School of Medicine, might receive my information?**    
We will share your name and address with KBM Group using a secure data transfer method, in order to obtain statistics on individuals similar to you, based on the zip code in which you live in. If required by law and/or necessary for oversight purposes, your information may be shared with Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies.  Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.  The Principal Investigator or study staff will inform you if there are any additions to the list in this document during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.  

**How long may the School of Medicine 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 may be held in a research database.  However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

• You have given written authorization  
• The University of Pennsylvania’s 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 information at any time.  You do this by sending written notice to the investigator for the study.  If you withdraw your permission, you will not be able to stay in this study.  Any information collected before your withdraw from the study may be used by the study team for research purposes.      
     
**What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study. You will have access to a copy, via your online dashboard, of this web-based Informed Consent and Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By clicking the button stating that you want to participate in the study, you will be considered to have consented to enroll. This means you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.  
     
**Who can I contact with other questions about the study?**   
You can contact the study team either by phone at 111-111-1111 or by email at example@waytohealt.org  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 with any questions, concerns, or complaints at the University of Pennsylvania by calling 111-111-1111.

**CONSENT**

This consent form will be saved to your online dashboard. From there, you can access and print copies of this consent form whenever you like.

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