HealthyMe Online Weight Management Education/HealthyMe at Home (HOME)

Informed Consent

NCT02057952

IRB Protocol #: 1201007860

Principal Investigator Name: Clark, Daniel

8/24/2015

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

HealthyMe Online weight Management Education - Accelerometry

STUDY PURPOSE:

You are currently participating in a research study that is testing a new way for people to take part in physical activity, health information, and health discussion groups. As part of that study, you are now being invited to wear an accelerometer. This is to monitor physical activity level.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of approximately 75 subjects who will be participating in this part of the study.

PROCEDURE FOR THE STUDY:

For this part of the study, we ask that you wear a watch-like device for two weeks. We are asking that as part of the two weeks, you make sure you wear the watch-like device for 7 continuous days for at least 23 of the 24 hours.

The device is not to be worn during bathing or showering. Please check that the device is charged at times you are not wearing it. If the device is not charged, or you are having difficulty in any way, call the study staff at the number provided to you.

RISKS OF TAKING PART IN THE STUDY:

While taking part in this study, the risks are being uncomfortable wearing the device. The device is a watch-like device that fits around the wrist.

To protect confidentiality, data will be kept in a protected computer file separate from all other study data and will not be used in combination with other identifier data.

BENEFITS OF TAKING PART IN THE STUDY:

The benefits to participation in this study are a sense of helping us learn. You are helping us to learn about physical activity patterns and how it relates to weight management.

ALTERNATIVES TO TAKING PART IN THIS STUDY:

The only alternative to taking part in this part of the study is to choose not to participate, which you have the right to do at any time.

CONFIDENTIALITY:

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), or the National Institutes of Health (NIH) who may need to access your medical and/or research records.

COSTS:

There is no cost for you to take part in this study.

PAYMENT:

You will receive an additional gift card for $50 if you wear the device for at least 7 continuous days, as well as at least 23 hours per day over the two week period.

CONTACTS FOR QUESTIONS OR PROBLEMS:

For questions about the study, contact the researcher Daniel Clark at 317-274-9292 or you may contact the research coordinator, Kimberly Hemmerlein, at 317-274-9106. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

For questions about your rights as a research participant or complaints about a research study, contact the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

VOLUNTARY NATURE OF STUDY:

Taking part in this part of the study is voluntary. You may choose not to take part in this part of the study or may leave the entire study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with your doctor, IU Health , or Eskenazi Hospital.

SUBJECT'S CONSENT:

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent statement to keep for my records.

SUBJECTS PRINTED NAME:

_____

SUBJECTS SIGNATURE:

_____Date:_____
(must be dated by the subject)

SIGNATURE OF PERSON OBTAINING CONSENT:

_____Date:_____