

UCSD HRPP approved research plan & consent language – GPS DEVICES

Risk Management Plan (Protocol #140510)

Participants will be informed that all responses and data collected from the GPS device will be kept confidential within the research team, and that no material that could personally identify them will be used in any reports or publications from this study. It will be explained to the subjects in clear terms, both verbally and in the written consent form, that their precise whereabouts for the entire time period the GPS device was worn will be known by the research staff. GPS data is not transmitted in real time and will be analyzed at some point later in time. Any potential risk of embarrassment or privacy due to GIS analysis is mitigated by developing environmental measures and indices from the GIS analysis that solely deal with physical activity and eating habits. No other environmental measures that may be indicative for other behaviors will be created. Additionally, environmental measures created from the GIS analysis will be used in statistical modeling at the group level only, and will not be individually mapped or visualized for publication purposes.

Participants will be told that the device belt can be worn under or over clothes. They will also be provided with different wrist band options for the wrist monitor and may choose which wrist band may work best for them. They will be provided with instructions on how best to wear the devices. They will also be told that the sensors are not considered to be medical devices or significant risk devices.

Risk Management Plan (Protocol #150336)

Participants will be told that the device belt can be worn under or over clothes. They will also be provided with different wrist band options for the wrist monitor and may choose which wrist band may work best for them. They will be provided with instructions on how best to wear the devices. They will also be told that the sensors are not considered to be medical devices or significant risk devices.

It will be explained to the subjects in clear terms, both verbally and in the written consent form, that their precise whereabouts for the entire time period the GPS device is worn will be collected. GPS data is not transmitted in real time. Any potential risk of embarrassment or privacy due to analysis with GIS data is mitigated by developing variables from the GPS data like the number of walking trips taken or average distance walked. Additionally, environmental measures created from the GIS analysis will be used in statistical modeling at the group level only, and will not be individually mapped or visualized for publication purposes.

Participants will be informed that all survey responses and data collected from the GPS device will be kept confidential within the research team, and that no material that could personally identify them will be used in any reports or publications from this study, unless explicit permission is given via written release. To reduce the risk to (and fear of) confidentiality, all subject records and data will be stripped of individual identifiers following data collection. We will assign each person a study ID and all records will be coded with the study ID rather than

personal identifiers. The code that links the study ID and the name will be stored in a separate place than the data file until all of the measurements are complete.

All data will be stored in locked cabinets and on a secure computer server at UCSD that can only be accessed by authorized members of the research team and university. Hard copies of informed consent statements and participant data will be kept in separate locked file cabinets. Information about subject participation may be shared with participating centers in order to promote its activities, including information like their name and attendance at events. Research staff will not share any identifiable research data collected at study assessments, like performance on the functioning tests.

Participants will also be told about the confidentiality procedures and that they have the right to refuse to answer questions or to terminate their participation in the study at any time without prejudice. The PI will assure that all human protections standards are met.

Consent Form (Protocols #140510 and #150336)

Description of Device: a location detecting device called a Global Positioning System (GPS). This is a device that records where you travel and is worn on a belt around your waist. You will wear this device while you are awake. The GPS device is about the size of a small cell phone. You will wear this device for 14 days. This device will be mailed to you. (Protocol #140510)

*Description of Device: **Wearing Sensors:*** You will be asked to wear small sensors for 7 days at the

beginning, 6, 12, 18 and 24 months. 2 sensors (called ‘accelerometers’) measure your movement and are worn at the waist and the wrist. A location detecting device called a Global Positioning System (GPS) records where you travel and tells us more about where and how you are active.

a. Two of the sensors (the waist accelerometer and the GPS) are worn on a belt around your waist. You will wear these devices for waking hours only. (Protocol #150336).

Risks: The risks involved in this study are minimal. You may also experience discomfort or a sense of loss of privacy as a result of revealing your location and daily activities or answering survey questions. The GPS device collects data on where you are at all times, just like information collected by a cell phone. This data is not transmitted or viewed in real time. (Protocol #140510)

Risks: The risks involved in this study are minimal. You may feel uncomfortable while wearing the study sensors, though there is no known health risks associated with wearing these sensors. You may also experience discomfort or a sense of loss of privacy as a result of revealing your location and daily activities or answering survey questions. The GPS device collects data on where you are at all times, just like information collected by a cell phone. This data is not

transmitted or viewed in real time. There is a small risk of loss of confidentiality. Your data is extremely important to us and the steps we take to protect it are described in the Confidentiality section below. If you feel uncomfortable with any study activity, you may discontinue participation at any time, either temporarily or permanently. (*Protocol #150336*).

Confidentiality: Research records will be kept confidential to the extent provided by law. All responses and data collected from the devices will be kept confidential within the research team, and no material that could personally identify you will be used in any reports or publications from this study.

Your data will be stored appropriately in locked cabinets and on a secure computer server in order to minimize the risk of loss of confidentiality. All data collected for this research that is stored on our secure computer will be identified by subject ID number only. Results of this study may be reported in scientific journals, meeting, and news media. None of these reports will use your name or use data that can point to any person who took part in the study. Strict security measures will be taken to insure that none of these procedures results in release of any information you provide us. (*Protocol #140510*).

Confidentiality: The information that you provide to UCSD staff will be kept confidential by the research staff to the extent allowed by law. Your data will be stored in locked cabinets and on a secure computer server that can only be accessed by authorized members of the research team and UCSD IRB. We will keep your name and address for purposes of follow up calls. You will not be personally identified in any reports or publications by UCSD resulting from this study, unless you provide permission via a written waiver. You give your permission for data to be used for analyses that have not yet been specifically planned at this time by researchers at UCSD and other institutes. Dr. Kerr will be responsible for deciding how your data will be used. You consent to such uses. Dr. Kerr, her associates, or her successors in these studies will keep your data and the information derived from it for an indefinite period. All efforts will be made to keep your data confidential but despite this there is some risk of loss of confidentiality. (*Protocol #150336*).