**Dual Data Collection: Study Information and Consent**

**TITLE: Dual Data Collection**

**PROTOCOL NO.:** Number

Protocol #

**SPONSOR:** RTI International

**INVESTIGATOR:** Robert Furberg

3040 Cornwallis Rd

Research Triangle Park, NC

**SITE(S):** RTI International Headquarters

Research Triangle Park

**STUDY-RELATED**

**PHONE NUMBER(S):** Robert Furberg

919 316 3726

**INTRODUCTION**

You are invited to participate in a research study. To be in the research study you must give your informed consent. The purpose of this form is to help you decide if you want to participate in this study. This form will review who can be in the study, the risks and benefits of the study, how we will protect your information, and who you can call if you have questions. Please read the information carefully. If you decide to take part in this research study, you will be given a copy of this signed and dated consent form.

**PURPOSE OF THE STUDY**

The study is being conducted by RTI International, a research organization located in Research Triangle Park, North Carolina.

Dual Data Collection is an exploratory pilot study. The purpose of this study is to demonstrate the feasibility of simultaneously collecting both passive and active data using the participant’s personal mobile device.

You are one of approximately one of twenty RTI employees being asked to participate in the two week data collection period. In order to be eligible for participation, you will need to own a mobile phone (specifically an iPhone) and be willing to download the necessary mobile applications (apps).

**DATA COLLECTION**

**Passive Data Collection**

This program will passively collect data through an app on your mobile phone. Passive data collected will include the following:

* Time
* Date
* GPS Coordinates
* Activities such as walking, running, cycling
* When the participant is using vehicular transit
* Number of times phone is picked up daily
* Application and battery usage.

**Active Data Collection**

From time to time, active data collection will be triggered on the your mobile phone in any of 3 ways: (1) you will be triggered to receive a survey prompt when you are within range of a specific location, (2) your movement into or out of areas of interest (such as buildings) will trigger the initiation of a survey prompt, (3) you will self-report and complete the survey without the use of a trigger to initiate a reminder prompt. Active data collected will include the following:

* Demographic Questions
* Electronic Remote Consent: Allowing the participant to consent to the data collection remotely from their mobile device.
* Daily Transit/Communing Questions
* Photographic Affect Meter of Sentiment: The participant will be shown a series of pictures and they will be able to select the picture that best describes how they are feeling.

Once the consent is signed, you will be asked to provide verbal confirmation to conduct a 10-minute pre-data collection survey. In addition, after the two weeks of data collection has concluded, you will be asked again to provide verbal confirmation to conduct a ten minute post-data collection survey.

**PROCEDURE**

**What will you be asked to do?**

* **Download a mobile app (free) and register an account:** You need to have the study app on your phone in order to participate in this study. This app will allow passive data to be collected throughout the two week data collection period. Everyone who enrolls will first complete an electronic registration process. The registration process can be done through the study app. Registration will include entering your name, email address and other general information about yourself. As part of this process you will also confirm your agreement to participate in the study.
* **Complete Surveys**: Upon the beginning and end of the two week data collection period you will be asked to complete a ten minute pre- and post- data collection survey. In addition, you will be asked to complete a series of surveys (both randomly triggered and self-initiated) throughout the two week data collection period. You have the right to refuse to answer any question.

**POTENTIAL RISKS**

Some survey questions may make you feel uncomfortable. Know that the information you provide is entirely up to you and you are free to skip questions that you do not want to answer.

Be safe – just as you would not text while driving, do not complete study surveys while driving. Wait until you are in a safe place!

You may have concerns about data security, privacy and confidentiality. We take great care to protect your information, however there is a slight risk of loss of confidentiality. This is a low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the research data to respect your privacy. However, even with removal of this information, it is sometimes possible to re-identify an individual given enough cross-referenced information about him or her. This risk, while very low, should still be contemplated prior to enrolling.

Data collected in this study will count against your existing mobile data plan. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan; however, all survey questions asked via the app must be completed using your mobile phone.

Participation in this study may involve risks that are not known at this time.

You will be told about any new information that might change your decision to be in this study.

**POTENTIAL BENEFITS**

There are no direct benefits to you; however, by participating you will help us develop a better understanding of the feasibility and processes for passive and active data collection using mobile phones.

**POTENTIAL COSTS**

There is no cost to you to participate in this study other than to your mobile data plan if applicable.

**DISCLOSURE OF INFORMATION**

Because information about you is personal and private, it generally cannot be used in a research study without your written authorization. If you sign this consent form, you will provide that authorization. You do not have to sign this form. But if you do not, you will not be able to participate in this research study.

**What personal information will be used or disclosed?**

Your personal information that may be used or disclosed in connection with this research study, will include, but is not limited to, your travel patterns, your browsing habits, your mobile phone metadata, and other telemetric information that is discernable from your mobile phone’s sensor. Your account information, study data and signed consent form may also be looked at and/or copied by designated personnel for regulatory and quality assurance.

**Who may use and disclose my data?** The study sponsor, investigators, study coordinators and study staff may use and disclose your personal information to do the research described above or as required by law.

**Who may receive or use the Information?** We will not disclose your identity in any reports about this study such as scientific publications or presentations. The parties listed in the preceding paragraph may disclose your information to other parties if required to do so by law.

**When will my authorization expire?** Your authorization for the use and/or disclosure of your health information will expire if you choose to withdraw from the research study.

**CONFIDENTIALITY**

We are committed to protect your privacy. Your identity will be kept as confidential as possible. Except as required by law, you will not be identified by name or by any other direct personal identifier.

To protect your privacy we will use a random code number instead of your name on all your data collected, analyzed, aggregated and released to researchers (except when compelled by law to disclose identities).

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Total confidentiality cannot be guaranteed.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You do not have to sign this consent form. But if you do not, you will not be able to participate in this research study. You may decide not to participate or you may leave the study at any time. Either of these decisions will not result in any penalty.

* You should not feel obligated to participate in this study.
* Your questions should be answered clearly and to your satisfaction.
* You have a right to download or transfer a copy of all of your study data.
* By agreeing to participate you do not waive any of your legal rights.

To withdraw from this study please contact the Study Principal Investigator, Dr. Robert Furberg by email rfurberg@rti.org or call 919 316 3726.

If you withdraw from the study, we will uninstall the apps within your mobile phone, stop collecting new data, and delete your study data from the research servers, but some copies of your data may not be able to be destroyed or deleted.

The Study Director or the sponsor may also withdraw you from the study without your consent at any time for any reason, including if it is in your best interest, you do not consent to continue in the study after being told of changes in the research that may affect you, or if the study is cancelled.

Your participation in this study is entirely voluntary. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time.

Please ask the researcher to explain anything you don’t understand before you make your decision. You should not join the research study until all of your questions are answered.

**SOURCE OF FUNDING**

RTI International is the sole source of funding for the Dual Data Collection study.

**QUESTIONS**

Contact Dr. Robert Furberg by email rfurberg@rti.org or call 919 316 3726 for any of the following reasons:

* If you have any questions about this study or your part in it, or
* If you have questions, concerns or complaints about the research

If you have questions about your rights as a research participant or if you have questions, concerns, input, or complaints about the research, you may contact RTI’s Office of Research Protection at 1(866)-214-2043. This is a toll-free number.

**CONSENT**

I have read about this research study (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study and I authorize the use and disclosure of my unnamed, coded data for use in research.

By signing this consent form I have not given up any of my legal rights.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM WILL BE GIVEN TO YOU.

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Signature of Adult Participant Date