

Northwell Health

Campus: Zucker Hillside Hospital

Consent for Participation in a Research Study

Title: Understanding Daily Fluctuations in Self-Regulation

Principal Investigator: Frederick Muench, Ph.D.

Sponsor: Robert Wood Johnson Foundation

Introduction

You are being asked to join a research study called, “Understanding Daily Fluctuations in Self-Regulation”. The purpose of a research study is to answer specific questions about your experiences and how they vary over time to help improve our understanding of health and well-being.

This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

Why is this research study being done?

The purpose of this study is to understand whether using a mobile health application that you download onto your mobile phone will help both you and us understand how your levels of concentration, self-regulation, and control vary throughout the day and in different circumstances, like when you are feeling happy or sad, or in the morning or evening. Although mobile phone apps have been made to help people monitor their behavior, we still do not know whether they work to improve your health. We also know very little about how genetics may or may not influence how people use their mobile phones. In this study, we ask you to come into our office to fill out questionnaires and then use the mobile application in your daily life to help us understand these questions.

You are being asked to participate in this study because we would like to know how our mobile application may or may not help us to understand how you self-regulate in different settings, and how your genetics might also play a role in self-control while using your mobile phone.

Why is this research?

This is a research study because we are collecting information on your mood, thoughts, and impulses using a mobile application. The mobile application is considered a device that has not been cleared by the FDA and is considered investigational.

How many people will take part in this study?

This research study hopes to enroll 120 men and women.

How long will you be in this study?

If you choose to take part in this study, the study period will last for a total of three weeks from the time you enroll in the study, but you will be able to use the mobile application until the conclusion of the research study on November 1, 2017.

What will happen in this research study?

In the first part of our research, you will come into our office for a two-hour research appointment and complete questionnaires along with computer and mobile game-like tests. Once you complete these tests, you will download a mobile app and use it twice a day for about 10 minutes per day (five minutes in the morning and five minutes in the evening). You can base your app usage around your schedule. We want to see if we can conduct this study solely by phone and to study how well the mobile app features work. We will use information about how you use the app to improve the app, but also provide you feedback on how your scores on the mobile tasks differ depending on certain factors, like time of day and mood.

You have already provided preliminary consent to be pre-screened using the online survey or in a brief telephone interview to determine if you are eligible to participate in this study. We are now requesting your written consent to confirm your eligibility and to participate in this study.

If you agree to participate in this study, you will undergo an assessment in order to confirm your eligibility for this study and to determine if this study is appropriate for you. The assessment that you will receive after signing this consent will determine if you are eligible. The assessment includes asking you questions about any mood fluctuations you have experienced and collecting information on risk-taking behavior. You will also need to be able to complete the separate questionnaires required as part of this study.

If it is determined that you are eligible to participate in this study, you participate in your only in-person appointment where you will complete questionnaires about yourself, feelings, behavior, and participate in computer and mobile game-like tests lasting about two hours.

During this appointment you will download a mobile application called the Digital Marshmallow Test and watch a video to help you understand how to use the app. After the appointment, you will complete a three to five-minute morning survey and game, as well as a three to five-minute evening survey and game for the next three weeks (21 morning surveys of three to five minutes each and 21 evening surveys of three to five minutes each). You will also be asked to complete a 10-minute survey at week **three** on the internet. You only have to come to our office one time. Below is a list of the procedures for this study:

Schedule of Events	
Prior to In-Person Assessment	
1	If you are interested in participating in this study, you will complete an online screening form to determine if you are eligible to participate in the study.
2	If eligible to participate in the study, you will undergo a review of the consent form with a member of the research team, and consent to participate in the study will be obtained after all of your questions have been answered by a member of the research team.
3	A member of the research team will schedule you to complete a one-time in-person assessment.
During the One-time In-Person Assessment	
4	You will come to our office for a two-hour assessment.
5	At the end of the assessment, you will watch a video on how to complete the mobile assessments that will occur during the next three weeks.
6	A member of the research team will assist you in downloading the mobile application onto your mobile phone and completing the sign-up process.
After In-Person Assessment	
7	You will complete daily three to five-minute morning and evening surveys, as well as one game per survey for three weeks.
8	You will complete a final 10-minute survey at the end of the three-week period.

Contents of In-Person Research Assessments: During your research assessment, you will be asked about your feelings, thoughts, behaviors, and other aspects about yourself. Some of these questions will be asked by a staff member and other questions will be presented on a computer. Computer questions will involve responding on the computer keyboard and/or to online assessments. We will also ask you to complete computer and mobile game-like tests. For example, we will ask you to pump up a digital balloon to try to receive points or digital currency, or choose your preference between two monetary options presented on the computer or mobile phone. This will take approximately two hours total for all assessments.

Mobile Phone Data Collection: Your mobile phone will be used for this study. You will download the mobile application where you will complete the questionnaires and mobile games and tests. The application will also collect data on your phone usage and activity. The application will not collect identifiable information about you or the content of your communication, but rather how often your phone is on or off or whether you complete the study surveys. We will send notices on your phone asking you to complete these tasks and surveys at specific times via push notifications through the mobile application. You can use the notification settings on your phone to control your notifications. We will inform you of these options during the study consent and review process.

Daily Online Questionnaires: You will be asked to complete some questions on your mobile phone at the in-person assessment and you will also be asked to complete two mobile questionnaires each day for at least the next three weeks. The questions will be about your mood,

thoughts, and behaviors over the recent past. In addition, you will be prompted to complete at least one game-like mobile task each time you complete the questionnaires. This will last for three weeks.

Text Message Data: You will also be asked a few questions via text message about your experience in the study. You will not be asked to provide identifiable information via text. This data is separate from the mobile phone application data collection.

Daily Mobile Phone Data: The app will track your use of the app and features in the app. This way the researchers can find out more about how often the app is typically used by participants, which specific features of the app are used, etc. In addition, we will collect other information about your mobile phone use such as when your phone is in use, when it is not, when you are using applications, the number of text messages sent and received, and your activity and movement. **It is important to note that we do not collect the content of your interactions with others, but rather when and how many things are happening on your phone. We will NOT access your personal contacts, text message content, personal photos, or websites visited; only the frequency and timing of your interaction with your phone.** During the training, we will show you these data collection features visually. This functionality is critical to the study, and these tracking devices are strictly necessary in order for you to use the app and to participate in the study. However, you may change your preference from time to time during the study, should you wish to do so by calling the researcher.

Three-Week 10-Minute Survey: At the end of the three-week period we will ask you to complete one final mobile questionnaire, which includes questions about your experiences during the study period along with the full version of the game-like tasks. This will take about 10 minutes.

Chart Review (Optional): If you were recruited from the Northwell Health Genotype and Phenotype Registry (GaP) study (PI: Peter K. Gregersen, MD), we ask you to give consent for us to review your data from that study to help better understand how genetics may influence self-regulation. This is an optional component of this study and you do not need to allow us to review this data in order to participate in this study. Please specify your choice below by *initialing* your selection.

_____ Yes, I consent for the PI to obtain my genetic data from the GaP study.

_____ No, I do not consent for the PI to obtain my genetic data from the GaP study.

In Case We Have Trouble Contacting You: To be in the study, we will ask you to provide the name and contact information of one person. The only reason we will contact them is to help us locate you if you move or are otherwise non-responsive to our outreach. No other information about you will be given to them, nor will we ask your contacts any questions.

Permission to Contact You Once the Study is Over (Optional): Sometimes, once the study is over, we realize we may have additional questions about your experience being in the study. We are asking your permission to re-contact you after the study to ask you questions about your experience of change and being in the study. This is an optional component of this study and you do not need to allow us to contact you once the study is over in order to participate in this study. You may withdraw permission for us to re-contact you at any time. Please specify your choice by *initialing* your selection.

_____ Yes, I consent to be re-contacted after my participation in the study is completed.

_____ No, I do not consent to be re-contacted after my participation in the study is completed.

What are the risks of the research study? What could go wrong?

There are some risks associated with this study. You may feel uncomfortable in answering some questions about your feelings, completing the tests about concentration, or discussing issues that are distressing when with the researcher. If you feel uncomfortable, you may choose to refuse to answer questions that you find hard to answer or talk about.

You may also feel some discomfort from completing questionnaires on your mobile phone when you are going about your day to day routines. You may get a notification at a time you don't want one which can be bothersome.

It is also possible that someone may know you are participating in a study about mood, concentration, and self-regulation through either the notifications you may receive or if you keep the application open on your phone. Even though there is no disease or conditions identified in this study, someone may learn you are participating in a research study. This could cause some embarrassment or self-consciousness.

The mobile app will also upload data from your smartphone. While it is minimal, it may slightly increase your data usage which may be subject to increased charges depending on your plan. **Be safe. Do not do study tasks while driving.** Wait until you are in a safe place to perform tasks.

You may have concerns about data security, privacy, and confidentiality. Your study data, including this consent, will be maintained in an encrypted database. Only a limited number of researchers will have access to any personally identifying survey or device information. Although we will use state-of-the-art technology to protect your information, there is a slight risk of loss of confidentiality; however, measures are in place to minimize this risk. This includes separating your personal information (information that can directly identify you, such as your name or phone number) from the app-use data that you provide to respect your privacy and maintain confidentiality. Even with removal of this information, it is sometimes possible to re-identify an individual. This risk, while very low, should still be considered before enrolling into this research study.

If you were recruited from the Northwell Health Genotype and Phenotype Registry (GaP) study (PI: Peter K. Gregersen, MD), we will combine the data that has already been collected from that study with our data to understand the role of genetics on self-regulation. You should be aware that there might be social and economic burden associated with collecting genetic information. Data from the GaP study might find an inherited gene, which puts you or a relative at risk for a genetic disorder in the future. Some people involved in genetic studies feel anxious about the possibility of carrying a gene that places them at risk for a disease or condition that may be passed on to their children. We will do our best to keep all information confidential. Only with your permission would we make this information available to others.

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

What are the benefits of this research study?

The possible benefits you may experience from this study include monitoring your mood and thoughts, and identifying the times of the day, mood, thoughts, and behaviors associated with when you are able to concentrate the least and most; however, this cannot be guaranteed. Information we learn about your condition may help others in the future as we hope to enhance this mobile application in order to help others.

If you do not want to take part in this research study, what are your other choices?

The alternative to participating in this study is not to participate. Your involvement in this research is entirely voluntary, and you can stop or withdraw from the study at any time. You do not have to participate in this study to receive information about your mood and feelings, and how they relate to your concentration and self-regulation.

Are there any costs for being in this research study?

There is no cost for using the mobile application in this study or the feedback you will receive. Because you will be receiving text messages as part of this study and may complete assessments using your smartphone, you may be subject to data overage usage charges per your smartphone data plan.

Will you receive any payments for participating in this research study?

As part of the study, we will provide you with payment as a way to compensate you for your time, effort, phone usage, and travel expenses. We will provide you with a payment of \$50 to complete the baseline in-person two-hour assessment, regardless of your eligibility for the study. At the end of the 21-day period, we will provide you with an additional \$25 for completing the daily mobile assessments plus an additional \$25 bonus if you complete at least 80% of the daily assessments and your 21-day assessment survey. Lastly, you may receive an additional \$25 for any additional surveys or game-like tasks completed during the in-person assessment. For example, you may be asked to complete five game-like tasks rather than three. This additional compensation would be for your added time and effort.

If the total payment you receive from Northwell Health, during this year, is equal to \$600 or more, the payment is required to be reported to IRS. Although this study does not pay \$600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling \$600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

If the research produces marketable products, will you receive any payment?

If this research produces a marketable product, there are no plans for you to receive any money.

What are your rights as a research participant?

Your participation in this project is voluntary. The quality of your medical care will be the same whether you join, refuse to join, or decide to leave the study.

If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor, or the Institutional Review Board (IRB, the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for the study visit,
- it is not in your best interest to continue on this study, and/or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately. Your consent to continue to take part in this study may be obtained again.

How do we protect confidentiality?

As you take part in this research project, it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use, and share that information. In order to protect your privacy, we will use a random

code instead of your name on all of your study data. This unique code cannot be used to directly re-identify you. Any survey or device data that identifies you (including name, birthdate, mobile phone number, etc.) will be removed before the data is transferred to researchers for the study. We will combine your study data, including survey response and task measurements, with those of other study participants. The combined data will be transferred to a computer program where all of the information can be used by researchers who have obtained permission to use the data obtained from this study. Your study data may be shared with other researchers outside of Northwell Health without any information that can identify you. Data will be stored in a manner that maintains strict information technology procedures to safeguard participant information and to prevent improper access.

What information will be collected and used for this study?

If you agree to be in this study, we will collect health information that identifies you such as your name, location, telephone numbers, birth date, email/internet protocol (IP) addresses, device ID, genetic information; and the results of tests, questionnaires, and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health.

Investigators will share information collected from this research study with:

- Other researchers

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies; and
- Representatives from Northwell Health’s Human Research Protection Program (the group of people that oversees research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?

If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at (516) 321-2100.

How long will your health information be kept?

There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it for as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?

If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you must send an email or letter to the Principal Investigator at the following address:

Dr. Frederick Muench
1010 Northern Boulevard, Suite 311
Great Neck, NY 11021
fmuench@northwell.edu

Your letter must state that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those who stay in it.

Will information about this study be available to the public?

Yes. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Does the investigator of this study receive money if you take part?

Funding for this research study is provided by the Robert Wood Johnson Foundation, with technology support from Cornell Tech and Sage Bionetworks. The funding is used to support the activities of the Division of Psychiatry Research and to pay back the Division for the costs of the study personnel. Compensation is *not* based upon the number of people enrolled in the study. If

your doctor is an investigator for this study, s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?

If you have any questions about the study, you may call the Principal Investigator, Dr. Frederick Muench at (917) 532-0623. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (IRB, the committee that oversees research at this institution) at (516) 321-2100. A signed copy of this consent form will be given to you.

A note from the study team:

We use the following questions to make sure that you fully understand what we are asking you to do as a participant in this research project. We will review this consent form and quiz with you. We wish to underscore that this quiz is not designed to challenge your commitment to the study or your treatment goals, but to ensure your safety and eligibility to participate.

Please read the following questions and select True or False:

1. I will be compensated for my participation in this study.
True False

2. Once the study begins, I cannot drop out no matter what the circumstances.
True False

3. If the researchers believe I pose a risk to myself or others, they may call the appropriate authorities to keep me and others safe.
True False

4. My data is being collected on a mobile application via questionnaires and tasks.
True False

5. My mobile phone data is being stored on a server hosted by Sage Bionetworks
True False

[SIGNATURE PAGE TO FOLLOW]

Summation/Signature

I have read the above description of the research study. I have been told the risks and benefits involved and all my questions have been answered to my satisfaction. A member of the research team will answer any future questions that I may have. I voluntarily agree to participate in this research study described above, and I know that I can withdraw from the study at any time without penalty. By signing this form, I have not given up any of my legal rights.

Signature of Participant

Printed Name of Participant

Date

Witness's Signature

Witness's Printed Name

Date

(Preferably someone not connected with the research project)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are or may be associated with this study, and to answer any further questions relating to it.

Investigator's Signature

Investigator's Printed Name

Date