Official Title of the Study: Investigating How Incentives Impact Engagement With an Online Mental Health Application (Neuroflow)

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University of Pennsylvania
Informed Consent Form

Investigating how Incentives Impact Engagement with an Online Mental Health Application (Neuroflow)

Title of the Research Study: Neuroflow App Wellbeing Study
Protocol Number:

Principal Investigator: Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, hjnuske@upenn.edu.

Emergency Contact: Cheryl Chang, Undergraduate at the University of Pennsylvania, 3901 Locust Walk, Philadelphia PA 19104, (516) 996-8699, cherylcc@sas.upenn.edu.
Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, heather.nuske@pennmedicine.upenn.edu

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You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. Regardless of whether you participate, you will not lose any benefits to which you are otherwise entitled. Before you decide whether to participate, you should know the purpose of the study, the possible risks and benefits of participating and what you will have to do if you decide to participate. This form is provided to you via the qualtrics survey and is downloadable as a pdf. If you would like a printed copy, please download the pdf and print it. You do not have to make a decision now; you can share this document with friends, family and professionals first.

If you do not understand what you are reading, do not sign it. Please reach out to Cheryl Chang, cherylcc@sas.upenn.edu, with questions regarding anything you do not understand. If you decide to participate, you will be asked to digitally sign this form and a copy will be given to you at your request. This form contains contact information and answers to questions about the study.

The purpose of the study is to understand how incentives (either points alone or points that can be exchanged for gift certificates) encourage engagement with an online mental health app (Neuroflow) for University students. Overall, the hope of this study is to help us understand how best to support mental health and wellness in university students.

What is the purpose of the study?

The primary purpose of the study is to understand how incentives (either points alone or points that can be exchanged for gift certificates) encourage engagement with an online mental health app (Neuroflow) for college students. The secondary purpose of the study is to compare participant mental health outcomes across differing groups of participants.

Why was I asked to participate in the study?

You were asked to participate in this study because you are a college student studying at the University of Pennsylvania or at another university in the United States of America, and you have access to a smartphone capable of downloading the Neuroflow application.

How long will I be in the study? How many other people will be in the study?

Participants will be in the study for approximately one month, including four weeks (28 days) of app use and completion of an online survey before and after this period. Participants are expected to spend approximately 1-15 minutes each day completing the daily check in and completing activities like watching videos, although you are free to spend as much time utilizing the app's activities and resources as you would like. A projected total of 40-100 people will be a part of the study. Please note that the entirety of this study is occurring remotely for participants and you will not be exposed to any other participant in this study.

Where will the study take place?

The study will take place remotely during your everyday life.

What will I be asked to do?

To participate in this study, you must complete the consent process. The consent process requires you to review and sign this consent form. If you decide to participate, you will need to have access to a smartphone and download the NeuroFlow app. You will be instructed on the steps to do so by a member of the research team.

In this study, you will first fill out the Qualtrics survey that includes a consent to contact, demographics survey, and consent form. After consenting to participate in the study, you will be

required to sign up for a 15 minute check in before and after the study in which we will go over the aims of the study and answer questions, if any, regarding the study or consent form. Following this, you will be randomly assigned to use Neuroflow either with points only or with points and the opportunity to exchange those points for gift cards. In both conditions, participants will begin by completing a consent form and a brief questionnaire with their contact information, which will be used to grant them access to the Neuroflow platform.You will then be expected to commit to using the NeuroFlow application at least a few minutes a day for 28 days and up to as much time as you would like

The data that will be collected is composed of the pre and post Qualtrics survey results as well as the usage metrics of the app. These user metrics will include identifying factors: first name, last name, gender, age, date of birth, and the applicable assignments to each participant - care team manager and behavioral health specialist. The first and last score, first and last date, and time between the first and last assessment dates for the measures of interest (PHQ-9, GAD-7, WHO-5, DERS) will be collected. Furthermore, the total activity number and the total activity rate across all measures will be collected. No additional data from or about participant phone usage or activities will be pulled as part of the study other than the usage metrics specified above, specific to Neuroflow. Please also note that data will be exported only after the complete 28 day trial and not on a continuous basis (we will not be using digital phenotyping).

What are the risks of participating in the study?
We anticipate very few risks associated with participating in the study. Participants may feel uncomfortable answering certain questions. As with any study taking personal information, there is the risk of a possible data breach that could expose information about participant's mental health. However, we will be deidentifying our dataset and any datasets with identifying information will be password locked. Only study personnel will have access to any data associated with the study. In the event of a mental health crisis, the NeuroFlow platform lists emergency resources within the app.

Please visit: https://www.neuroflow.com/terms-of-service/ for the Neuroflow application terms of service.

How will I benefit from the study?
Participants enrolled in psychology courses or any other courses at the University of Pennsylvania that use the SONA system may elect to participate in the study for credit. College students from other US universities may also be invited to participate. Participants may only

receive credit by signing up through the University of Pennsylvania's SONA study pool. SONA credits will be disbursed by the semester deadline.

Additionally, our study will allow participants to engage with a mental health platform where they can learn skills to manage their mental health and improve their mental well-being. Additionally, through the study, we will gain a better understanding of which incentives increase engagement on a mental health platform, which can inform more effective delivery of mental health resources and information. Online mental health platforms, such as NeuroFlow, have the potential to improve wellbeing in college students, which would provide a major benefit to public health.

What other choices do I have?

Your alternative to being in the study is to not be in the study. Not participating in the study will not affect you in any way.

What happens if I choose not to join the research study?

You may choose to join the study or you may choose not to join the study. If after beginning the study, you decide not to continue your participation, you may choose to stop participating. Your participation is voluntary.

Your decision on whether or not to participate in this research will not affect your relationship with the University of Pennsylvania and related services. Your student status will also not be affected by your decision to participate or not participate in this study. You can end your participation at any time. You can choose to stop participating in the study at any point if you feel uncomfortable, however, we do ask that you inform us of your decision.

When is the study over? Can I leave the study before it ends?

The study will last approximately one month from the start date (which is determined to be the first day a participant completes the mental health diagnosis and app check in) and the app use period will be for 4 weeks (28 days).

You may drop out of the study at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Data will be exported only after the complete 28 day trial and not on a continuous basis (we will not be using digital phenotyping) and as such

participants who choose to leave the study will not have any information from them kept. Any potential information from participants who chose to withdraw from the study earlier will be destroyed through deleting their pre-study Qualtrics survey responses and removing their names from the master de-identifying password protected excel file located in the Penn box.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely finished.

If you no longer wish to be in the research study, please contact the Research Assistant, Cheryl Chang, at (516) 996-88699 or the Principal Investigator, Heather Nuske, PhD, at (215) 746-6041. You can withdraw from the study by verbally stating that you do not wish to participate in the Neuroflow App Wellbeing Study. Clearly state your name and address and a written verification of your removal from the study will be sent to you within 30 calendar days. Alternatively, if you would prefer to provide written notification of withdrawal you may send this information to:

Dr. Heather Nuske
Penn Center for Mental Health
3535 Market Street, Floor 3
Department of Psychiatry
Perelman School of Medicine
University of Pennsylvania
Philadelphia
PA 19104

Return written verification of your removal from the study will be sent to you within 30 calendar days.

How will confidentiality be maintained and my privacy protected?

All information you provide will be kept confidential, except as required by law. Confidentiality will have to be broken if you express a current plan to harm yourself or others, or if you report that you have committed child abuse or neglect. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. The IRB has access to study information. Any documents you sign where you can be identified by name will be kept in a locked file cabinet in a locked office at the

University of Pennsylvania. Only the Principal Investigator and the study coordinators will have the key to this file cabinet. These documents will be kept confidential.

All members of the research team will receive training on policies and procedures with respect to the privacy of protected health information. This education is provided to ensure Health Insurance Portability and Accountability Act (HIPAA) regulatory compliance and to implement improved privacy practices. All faculty, staff, student assistants and consultants at the University of Pennsylvania who may come into contact with these data will be required to sign a Confidentiality Agreement. By signing the Confidentiality Agreement, the faculty member, staff member, student assistant, or consultant will agree to abide by the Center's policies and procedures. In addition, staff, student assistants and consultants assigned to specific projects may be required to sign data security agreements specific to those projects.

To protect your confidentiality, we will not link any personal identifiable information (including your name or picture) to your comments or surveys. Your comments will be used for research purposes only. No information that you disclose will be shared with anyone outside the research project, except as required by law. All study records will be held in a locked file cabinet, and only personnel involved in the research will have access to the data. No identifying information will appear when we present this study or publish its results.

Please note that de-identified information will be collected about you for this study. The information that will be collected include responses to health questionnaires, responses to ease of use questionnaires, and data on how you engage and use content in the platform. This de-identified information will be seen by the people involved with this research. Steps will be taken to protect your identity, and information collected will be kept secure. All information collected will be protected by HIPAA (Health Insurance Portability and Accountability Act), this is the law that protects your personal health information. To do this study, we need to collect and analyze your data. This will be done by personnel at University of Pennsylvania and NeuroFlow, Inc. for the purpose of this research, data will not be shared outside these two entities. The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified. Your private information, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

Future Use of Data: Information that can identify you will be kept permanently in a computer database in the University of Pennsylvania. Only the study researchers and those working with them on this study will be able to see information that can identify you. If your information is

shared outside of the University of Pennsylvania, no identifiable information will be included. If you leave the study, you can ask to have the data collected about you removed.

What happens if I am injured from being in the study?

If you are injured or feel emotional discomfort while participating in the study you may contact the Principal Investigators or the emergency contact name on the first page of this form. They can go over things with you, let you know of resources that may be available and give you information on what you need to do. In case of injury resulting from this study, you will not lose any legal rights by signing this form. Also, you may contact your own doctor, counselor or seek treatment outside of the University of Pennsylvania. Bring this document, and tell your doctor/counselor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the numbers on the first page of this form for information.

If you are injured or feel emotional discomfort from being in the study, the appropriate care will be provided without cost to you through the University of Pennsylvania, but financial compensation is not otherwise available from the University of Pennsylvania. If you are injured or feel emotional discomfort while in the study but it is <u>not related</u> to the study, you and your insurance company will be responsible for the costs of that care.

Will I have to pay for anything?

There are no costs associated with participating in this study, beyond your time to complete the daily check-ins on NeuroFlow and your decision to complete any supplemental activity on the app. NeuroFlow is a free app.

Will I be compensated for participating in the study?

There will be no financial compensation for participation in this study. For students enrolled at the University of Pennsylvania who registered through the SONA system, 4 credits will be award after the completion of the study and prior to the end of the semester.

Additionally, I will not be compensated for enrollment in the study but if randomized to the controlled group I will be able to cash in accrued points received for completing app activities for gift cards(maximum points = 1000 per month = ~$10).

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns, or complaints regarding your participation in this research study, or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. 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 (215) 898-2614.

If you have any questions or there is something you do not understand, please ask. If you would like a copy of this consent document, please check the applicable qualtrics question box or contact the researchers (contact information listed on the first page).

By signing (digitally or physically) this form, you are indicating that you have had your questions answered, you agree to take part in this research study and that you consent to your participation. You are also agreeing to let the University of Pennsylvania use and share your health information as explained above. If you don't agree to the data collection, use and sharing of your health information, you cannot participate in this study.

If you have any questions or wish to contact the Industry Review Board at the University of Pennsylvania, please call 215-573-2540 or email PROVOST-IRB@pobox.upenn.edu.