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

**NCT Number:** NCT05121675

**Date of the Document:** October 16, 2021

# Protocol Details

**Basic Info**

| | |
|---|---|
| Confirmation Number: | **deiffibj** |
| Protocol Number: | **849894** |
| Created By: | **NUSKE, HEATHER J** |
| Principal Investigator: | **NUSKE, HEATHER J** |
| Protocol Title: | **Investigating how Incentives Impact Engagement with an Online Mental Health Application (Neuroflow)** |
| Short Title: | **Neuroflow App Wellbeing Study** |
| Protocol Description: | **The primary research goal of the proposed project 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 at the University of Pennsylvania. The secondary aim is to compare participant outcomes across the groups of participants.** |
| Application Type: | **EXEMPT Category 3** |

**Resubmission***
Yes

**Hospital Sites**
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

## Study Personnel

### *Principal Investigator*

| | |
|---|---|
| Name: | **NUSKE, HEATHER J** |
| Dept / School / Div: | **4412 - PS-Psychiatry** |
| Campus Address Mail Code | **3309** |
| Address: | **OFFICE BLDG STE 100**<br>**3535 MARKET ST** |
| City State Zip: | **PHILADELPHIA PA 19104-3309** |
| Phone: | **215-746-6041** |
| Fax: | |
| Pager: | |
| Email: | **hjnuske@upenn.edu** |
| HS Training Completed: | **Yes** |
| Training Expiration Date: | |
| Name of course completed : | **CITI Protection of Human Subjects Research Training - ORA** |
| GCP Training Completed: | **No** |
| Training Expiration Date: | |
| Name of course completed : | |

## *Study Contacts*

| | |
|---|---|
| Name: | **PALERMO, EMMA H** |
| Dept / School / Div: | **8760 - Research Services** |
| Campus Address<br>Mail Code | |
| Address: | **180 E BENEZET ST** |
| City State Zip: | **PHILADELPHIA PA 19118-0000** |
| Phone: | **215-247-0977** |
| Fax: | |
| Pager: | |
| Email: | **epalermo@sas.upenn.edu** |
| HS Training Completed: | **Yes** |
| Training Expiration Date: | |
| Name of course completed : | **CITI Protection of Human Subjects Research Training - ORA** |
| GCP Training Completed: | **No** |
| Training Expiration Date: | |
| Name of course completed : | |

| | |
|---|---|
| Name: | **CHANG, CHERYL** |
| Dept / School / Div: | **312 - The College** |
| Campus Address<br>Mail Code | |
| Address: | **4641 Overbrook St** |
| City State Zip: | **Little Neck NY 11362-1111** |
| Phone: | |
| Fax: | |
| Pager: | |
| Email: | **cherylcc@sas.upenn.edu** |
| HS Training Completed: | **Yes** |
| Training Expiration Date: | |
| Name of course completed : | **CITI Protection of Human Subjects Research Training - ORA** |
| GCP Training Completed: | **Yes** |
| Training Expiration Date: | **09/13/2024** |
| Name of course completed : | **CITI Good Clinical Practice (GCP) - OCR** |

**Other Investigator**

None

**Responsible Org (Department/School/Division):**

4412 - PS-Psychiatry

### *Key Study Personnel*

| | |
|---|---|
| Name: | **DESWERT, SKY** |
| Department/School/Division: | **PS-Mental Health Services** |
| HS Training Completed: | **Yes** |
| Training Expiration Date: | |
| Name of course completed: | **CITI Protection of Human Subjects Research Training - ORA** |
| GCP Training Completed: | **Yes** |
| Training Expiration Date: | **11/11/2025** |
| Name of course completed: | **Good Clinical Practice (GCP) Simulation** |

| | |
|---|---|
| Name: | **BROWN, ALYSSA K** |
| Department/School/Division: | **PS-Mental Health Services** |
| HS Training Completed: | **Yes** |
| Training Expiration Date: | |
| Name of course completed: | **CITI Protection of Human Subjects Research Training - ORA** |
| GCP Training Completed: | **No** |
| Training Expiration Date: | |
| Name of course completed: | |

**Disclosure of Significant Financial Interests***
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

**Penn Intellectual Property***
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania? Please refer to the Patent and Tangible Research Property Policies and Procedures.
No

**Certification**
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

## HRPP

**Human Source Material***
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)? IF YES, consult the EHRS web site: www.ehrs.upenn.edu/programs/bio/bbpathogens.html for information on OSHA Bloodborne Pathogens requirements (training, vaccination, work practices and Exposure Control Plan). If you have questions, call 215-898-4453.
No

**Image Guided Biopsies***
Does the research involve imaging guided biopsy? IF YES, please contact the Clinical Imaging Core.

See https://www.med.upenn.edu/cbi for more details. Any questions should be directed to the Director of Research Operations, Dept of Radiology, Kathleen Thomas.
No

**HIPAA / Protected Health Information**
Does the research proposal involve accessing (viewing / using), collecting, or disclosing of protected health information (PHI) directly from participants or their medical or dental record for research purposes?
No

**HIPAA / Protected Health Information**
Does the research proposal involve accessing (viewing / using), collecting, or disclosing of protected health information (PHI) directly from participants or their medical or dental record for research purposes?
No

**Remote Study Visits**
Does the research proposal involve conducting research visits remotely via any type of video conferencing software?
No

**Remote Study Visits**
Does the research proposal involve conducting research visits remotely via any type of video conferencing software?
No

**CHPS Resources***
Does the research involve CHPS resources?
No

**HUP Inpatient Nursing Resources**
Does this research include an inpatient admission at HUP?
No

**Pathology and Laboratory Medicine Resources***
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

**Research Involves Apheresis, Cell Collection, and/or Blood Product Collection***
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

**Research involving blood transfusion or drug infusions***
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

**HUP Perioperative and Procedural Services ***
Does the research require the following: The collection of tissue, fluid, or blood in HUP Perioperative and Procedural Services ORThe administration of medications in HUP Perioperative and Procedural Services?This is inclusive to all phases of Perioperative care: pre-operative, intraoperative, and postoperative periods in all HUP Perioperative Procedure locations.If you have questions, please contact: HUPPeriopClinicalResearch@PennMedicine.upenn.edu
N/A

**Trial in Radiation Oncology**
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

**Study in Radiation Oncology**
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

**Use of UPHS services***
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures , whether considered routine care or strictly for research purposes? (UPHS includes all Penn hospitals and clinical practices, including the Clinical Care Associates network of community practices). Examples of UPHS services/tests/procedures includes the Clinical Translational Research Center (CTRC), laboratory tests, use of the pathology lab, cardiovascular imaging tests or radiology imaging tests (whether being billed via the Service Center or through UPHS), other diagnostic tests & procedures and associated professional services, etc.
No

**Veteran's Affairs (VA) Patients or Subjects**
Does your study involve data from Veteran's Affairs (VA) patients or subjects?
No

**If yes, was this approved by the Philadelphia VA?**

No

**Out of State Research**
Will any Penn personnel conduct any research activities outside of the State of Pennsylvania?
No

**Research involving Virtua Health**
Will any Penn personnel conduct any research activities at a Virtua Health site location, OR in collaboration with Virtua Health System personnel, OR using any Virtua Health System resources (e.g., medical records)?
No

**Primary Focus***
Clinical Trial (prospectively assigning subjects to health-related interventions to evaluate outcomes)

## *Protocol Interventions*

| | |
|---|---|
| x | **Sociobehavioral (i.e. cognitive or behavioral therapy)** |
| | **Drug** |
| x | **Device - therapeutic** |
| | **Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)** |
| | **Surgical** |
| | **Diagnostic test/procedure (research-related diagnostic test or procedure)** |
| | **Obtaining human tissue for basic research or biospecimen bank** |
| x | **Survey instrument** |
| | **None of the above** |

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

# Sponsors

### *Business Administrator*

| | |
|---|---|
| Name: | **COLANGELO, EILEEN E** |
| Dept / School / Div: | **4423 - PS-Mental Health Services** |
| Phone: | **215-746-6666** |
| Fax: | **215-573-0759** |
| Pager: | |
| Email: | **emerg@pennmedicine.upenn.edu** |

### *Department budget code*

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

### *Funding Sponsors*

**Funding sponsors billing address**
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

**Funding sponsors gift**
Is this research being funded by a philanthropic gift?

**Project Funding***
Is this project funded by or associated with a grant or contract?
No

**Sponsor Funding**
Is this study funded by an industry sponsor?

**Status of contract**

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

# Protocol

### *Objectives*

**Overall objectives**
Primary: Differences in user engagement and retention over four weeks (28 days) by two forms of behavior economics incentives (either with its usual system of point incentives or with financial incentives). User engagement will be measured by the number of active users, the number of activities completed, and completion of daily mood and sleep ratings. Secondary: Differences in user anxiety, depression, well-being and emotion regulation levels after engagement with the NeuroFlow app, and how it varies by the incentives used for app engagement.

**Background**
As mental health awareness and intervention has gained more traction throughout the years, applications - such as NeuroFlow - have emerged in an effort to facilitate aid to those who are unable to afford or access alternative mental health care methods (Huckvale et al, 2020). However, over 95% of mental health and wellness applications have not actually been studied (Lecomte et al., 2020).

Additionally, a large portion examines user adoption of various mental health applications based on different factors, leaving a gap in research regarding client engagement and interest post-installation (Huang and Bashir, 2017). Thus, despite promises, applications for promoting mental health often do not achieve their intended goals due to lack of sufficient client engagement/interest. In order to address this discrepancy, the use of financial incentives and other incentives from the field of behavioral economics may help (Beidas et al., 2019). As an application, NeuroFlow embeds behavioral economic principles to increase motivation and engagement with the application (such as personalized pop-up notification reminders and app gamification including points accrual for activity completion and celebratory messages for meeting points thresholds) and also provides financial incentives whereby points accrued can be redeemed into gift cards for popular outlets such as Amazon. However, it is not clear if this financial incentive increases engagement or has knock-on effects for mental health and wellbeing over and above the behavioral economics incentives per se. In this study, we will conduct a pilot two-arm randomized controlled trial where we will examine the effect of a treatment group (NeuroFlow app with behavioral economics and financial incentives vs. NeuroFlow app with behavioral economics incentives only) on application engagement and mental health and wellbeing (anxiety and depression symptoms, sleep, self-regulation and wellbeing). The purpose of this study is to gain an understanding of how incentives encourage participation and engagement with an online mental health platform, NeuroFlow.

### *Study Design*

**Design**
This is a two-arm randomized controlled trial assessing the impact of various incentives (points or monetary) on user engagement and retention on the mobile mental health platform, Neuroflow. This study will utilize a block randomization procedure to assign subjects to one of two treatment groups and a between-subjects design in order to understand how the different incentives impact user engagement with the platform. After consenting to participate in the study, participants will be asked to complete the NeuroFlow daily check in for 28 consecutive days, incentivized by either points only, or points redeemable for gift cards (monetary incentive).

**Study duration**
Participants will be actively in the study for approximately one month including four weeks (28 days) of app usage,with time to fill out the pre and post Qualtrics survey to examine changes in mental health related outcomes. Overall, participant recruitment for the study will span the Fall 2021 and Spring 2022 semesters.

## Characteristics of the Study Population

**Target population**
The target population for this study are college students either at the University of Pennsylvania or other US universities. Participants will be included if they have a smartphone and are willing to download and use the Neuroflow app throughout the duration of the study.

**Subjects enrolled by Penn Researchers**
100

**Subjects enrolled by Collaborating Researchers**
0

### *Vulnerable Populations*

| | |
|---|---|
| | **Children Form** |
| | **Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form** |
| | **Fetuses and/or Neonates Form** |
| | **Prisoners Form** |
| | **Other** |
| x | **None of the above populations are included in the research study** |

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Participant recruitment**
Please describe the plan to equitably identify and recruit a diverse group of participants that is reflective of the population under study. If this is a multicenter protocol, the recruitment plan should describe the local (Penn) site's plan. Describe:how potential participants may be identified (review of medical records, Slicer Dicer, DAC reports including referrals from physician offices and clinics);who may approach potential participants;methods to achieve sample diversity and inclusiveness;what information may be presented to or discussed with them; andthe context and setting in which recruitment will happen.
Subjects will primarily be recruited from the University of Pennsylvania through the online participant study pool, SONA. Individuals will receive a link to a web-based form after signing up where they will give their consent to participate in the study. If participant recruitment through SONA is insufficient to meet our target sample size, we will additionally recruit other University students from the United States through class email lists, social media platforms (e.g., Facebook class groups), and flyers (with a scannable barcode and detablable pieces with contract information) around campus. No participants under the age of 18 will be enrolled.

**Recruitment Materials**
Is the research team using any recruitment materials? These may include but are not limited to: phone call scripts, radio/video scripts, flyers/brochures, internet postings, email, letters to potential participants, letters to patient physicians, My Penn Medicine (MPM), other direct messaging, etc. For guidance regarding recruitment materials, please review the IRB's guidance on Participant Recruitment Materials online:https://irb.upenn.edu/recruitment
No

**Use of Penn Media & Social Media Services**
Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
Yes

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting research recruitment text.NOTE: Penn Medicine must utilize one of the centralized PM Facebook Pages:ClinicalResearch@Penn Facebook pagePenn Medicine Facebook page@PennCancer Facebook pageAll clinical research paid Facebook ads must be listed on Clinical Research @ Penn Facebook page,www.facebook.com/ClinicalTrialsAtPenn. Exceptions to the above must get approval from the Penn Medicine Social Media Committee: pennmedicinesocialmediacommittee@uphs.upenn.edu.
Social Media Text:  Facebook: Researchers at @UPenn are seeking college students studying at the University of Pennsylvania who have access to a smartphone capable of downloading the Neuroflow application to spend approximately 1 minute each day completing the daily check in for 28 days and a maximum of 15 minutes filling out a pre and post study qualtrics survey. This study aims to understand incentives that encourage engagement with a mental health app in order to promote mental wellness

among college students. For more information: Please contact Cheryl Chang, Research Assistant at the Penn Center for Mental Health, at cherylcc@upenn.sas.edu [link to flyer] Twitter: @UPenn seeking college students with smartphone access to download Neuroflow app to help understand the role of incentives in user engagement/promote mental wellness. Interested? Contact Cheryl Chang, @Penn Center for Mental Health, cherylcc@upenn.sas.edu [link to flyer] Flyers have been uploaded under the Recruitment Materials tab.

***The following documents are currently attached to this item:***

**Subject recruitment (neuroflow-flyervertical3.pptx)**

**Subject recruitment (neuroflow-flyerhorizontal3.pptx)**

**Subject compensation***
Will subjects be financially compensated for their participation?
No

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document**

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 awarded after the completion of the study and prior to the end of the semester. Additionally, participants will not be compensated for enrollment in the study but if randomized to the controlled group they will be able to cash in accrued points received for completing app activities for gift cards(maximum points = 1000 per month = ~$10).

# Study Procedures

**Suicidal Ideation and Behavior**
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)? Centeral nervous system(CNS) effect: the ability of a test article to enter into and potentially interact with the central nervoous system (brain and spinal cord). Clinical Investigation: Any experiment that involves a test article and one or more human subjects that either is subject to requirements for prior submission to the Food and Drug Adminstration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to the FDA under these sections of the act, but, the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
No

**Procedures**
This study is a two-arm pilot randomized controlled trial to assess differences in user retention and usage rates associated with two incentive structures within the NeuroFlow app (I.e., general structure versus financial compensation). We will assess user engagement with utilization data (ie., daily, weekly, and monthly active users) and measures of the total number of activity counts completed by a user. After consenting to participate in the study, participants 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. In both recruitment methods, participants will be required to sign up for a 15 minute check in and check out meeting before and after the trial to answer participant questions regarding the app/app set up or concerns about the consent form. Furthermore, a Qualtrics survey will also be dispersed to participants to be taken during this time along with an initial baseline assessment (to be administered in the NeuroFlow app). Baseline and post-app usage Qualtrics survey links will also be sent with measures

(Generalized anxiety disorder (GAD), Patient Health Questionnaire (PHQ), World Health Organization-Five Well-Being Index (WHO-5), and Difficulties in Emotion Regulation Scale (DERS)) to participants in order to assess differences in user retention. In both conditions, participants will use the Neuroflow app throughout the duration of the 4-week study (28 days). Participants will be sent a push notification each day through the app to complete their daily activities, which could include surveys, videos, or skill-based practice materials. With the collaboration of the Neuroflow team, the usage metrics of the app will be pulled after the end of the study. The user metrics of interest are identifying factors that include first name, last name, gender, age, date of birth, and the applicable assignments to each participant - care team manager and behavioral health specialist. Additionally, 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). 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.

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Deception**
Does your project use deception? Deception could be considered any direct misinformation presented to the subject or omission of key information pertaining to the design or nature of the project.
No

**International Research**
Are you conducting research outside of the United States?
No

**Analysis Plan**
The anticipated statistical analyses to be conducted for this study is a Linear-mixed effects model (LMMs). These models will be used to examine the effect of different incentives (behavioral economics and financial vs. behavioral economics only) on user engagement (measured by the number of active users, the number of activities completed, and completion of daily mood and sleep ratings) and retention. We will also examine the effect of incentive type on secondary mental health outcomes such as anxiety symptoms (GAD-7total score), depression symptoms (PHQ-9 total score), wellbeing (WHO-5total score)and emotion regulation (DERS total score).

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Subject Confidentiality**
There will be no paper-based records kept for this study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. Whenever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys. The information that will be collected include responses to health questionnaires, responses to ease of use questionnaires, and data on how participants 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 participants identity through de-identifying information, 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 participants personal health information. To do this study, we need to collect and analyze participant 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 identifying information that will be collected includes participant first and last name, email, phone number and date of birth (which is needed in order to set up participant accounts), and Qualtrics survey responses with other demographic information. We will also have an excel sheet that contains identifying data in connection to assigned participant ID. These identifying data will be kept in a password protected excel sheet which will be stored in Penn Box and kept separate from study data. In order to de-identify data,

we will take a participants assigned participant ID number in place of any identifying data which will be connected to their deidentifying data (detailed below). De-identified study data that includes baseline assessment and post app usage assessment results via the Neuroflow application will be collected about participants for this study. For people who consented to have their contact information on file for future research, we will store it in a password protected excel sheet. For other participants, all identifying data will be destroyed within one year from their participation end date. The information from this study may be published in scientific journals or presented at scientific meetings, but participants will not be personally identified. participant private information, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without participants additional permission

**Sensitive Research Information***
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record? [NOTE: This does not apply to: 1) research information that would not normally be included in the electronic medical record or 2) information that is in the electronic medical record as part of clinical care.]
No

**Disclosures**
Will any data or specimens from Penn participants OR other research generated work product (e.g., intellectual property) be disclosed to any individuals, entities, or vendors, etc. outside of Penn?
No

### *Data Protection**

| | |
|---|---|
| x | **Name** |
| | **Street address, city, county, precinct, zip code, and equivalent geocodes** |
| | **All elements of dates (except year) for dates directly related to an individual and all ages over 89** |
| x | **Telephone and fax number** |
| x | **Electronic mail addresses** |
| | **Social security numbers** |
| | **Medical record numbers** |
| | **Health plan ID numbers** |
| | **Account numbers** |
| | **Certificate/license numbers** |
| | **Vehicle identifiers and serial numbers, including license plate numbers** |
| | **Device identifiers/serial numbers** |
| | **Web addresses (URLs)** |
| | **Internet IP addresses** |
| | **Biometric identifiers, incl. finger and voice prints** |
| | **Full face photographic images and any comparable images** |
| | **Any other unique identifying number, characteristic, or code** |
| | **None** |

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

# Consent

### *1. Consent Process*

**Overview**
Participants will receive a brief introduction to study via the description section of the SONA system or via the flyers that will be distributed for recruitment. Participants will all need to contact the study team via SONA or other methods of recruitment to express interest in participating before any next steps commence. All participants will have access to a brief introduction of the study aims and objectives via the first page of the mandatory Qualtrics form that must be filled out in order for study participation as well. In both cases, participants will be required to sign up for a 15 minute check in and check out meeting before and after the trial to answer participant questions regarding the app/app set up or concerns about the consent form. Informed consent will take place digitally for this study. An outline of the Qualtrics form is that, after providing a brief introduction of the study, participants will be prompted to fill out a consent to contact form and a brief demographics survey before being presented with a consent form. After reading through it, participants will have to select I have read the above terms and consent to participate in this study before they will be eligible to continue with the study. Participants will be informed that they can withdraw from the study at any time without any consequences by emailing the PI or any other researchers affiliated with the study. The consent form will be written in comprehensible language and we expect all participants to be able to give their own consent. Participants will not receive an invitation to the NeuroFlow platform until they have consented to participate in the study.

# Risk / Benefit

**Potential Study Risks**
We anticipate very few risks associated with participating in the study. Participants may feel uncomfortable answering certain questions, but all questions will be optional and there will be no penalties or consequences associated with choosing to opt out of providing certain information. As with any study taking personal information, there is the risk of a possible data breach that could expose information about participants 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 or reports of suicidal ideation, the NeuroFlow platform lists emergency resources within the app.

**Potential Study Benefits**
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.

**Risk / Benefit Assessment**
There is minimal to no risk associated with this study, and the benefits of improving college student mental health and developing an understanding of the incentives that increase mental health platform engagement and utilization is a major benefit associated with the study. Therefore, the benefits of the study outweigh any potential risks associated with the study.

# General Attachments

***The following documents are currently attached to this item:***

**Additional forms (modificationform2019.6-clean_01.doc)**

**Additional forms (citi_emma.pdf)**

**Recruitment materials (neuroflow-flyerhorizontal.pptx)**

**Additional forms (deswert_citi_2021.pdf)**

**Additional forms (brown_citi_2021.pdf)**

**Additional forms (chang_citi_2021.pdf)**

**Additional forms (nuske_citi_2019_05.pdf)**

**Additional forms (neuroflow-termsofservice.docx)**

**Additional forms (gad-7.doc)**

**Additional forms (phq-9.pdf)**

**Additional forms (who-5.pdf)**

**Additional forms (ders1.pdf)**

**Questionnaires (demographicquestionnaire.doc)**

**Questionnaires (screenerandconsenttocontact.docx)**

**Recruitment materials (neuroflow-flyervertical.pptx)**

**Cover Letter (neuroflow-revisioncoverletter_hn1.docx)**

**Informed consent form (neuroflow-consentformsfinalre2.docx)**

**Informed consent form (neuroflow-consentformsfinalre-trackedchanges1.docx)**